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(54) **FLEXIBLE CANOPY VALVE REPAIR SYSTEMS AND METHODS OF USE**

(71) Applicant: **MEDTRONIC VASCULAR, INC.**, Santa Rosa, CA (US)

(72) Inventors: **Matthew Genovese**, Windsor, CA (US); **Jeffrey Sandstrom**, Scandia, MN (US); **Russell Pribanic**, Roxbury, CT (US); **Thomas Mcpeak**, Caledonia, MN (US); **Vania Lee**, Circle Pines, MN (US); **Dermot O'Brien**, Galway (IE); **James Calvin Allan**, Boise, ID (US)

(73) Assignee: **MEDTRONIC VASCULAR, INC.**, Santa Rosa, CA (US)

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(58) **Field of Classification Search**

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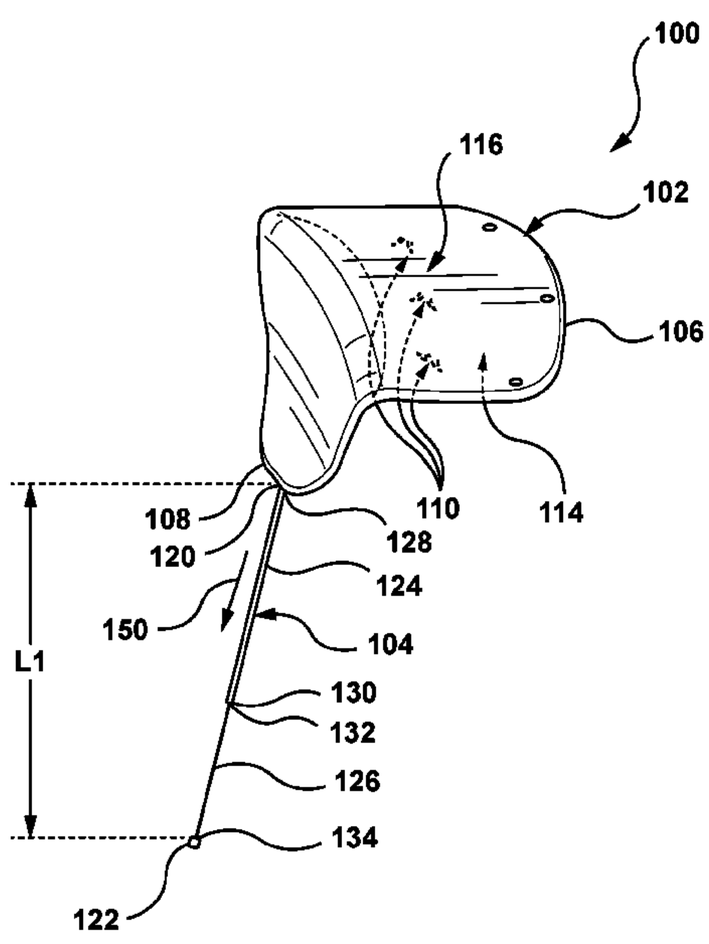
Primary Examiner — Suba Ganesan
(74) *Attorney, Agent, or Firm* — Meddler Ferro Woodhouse & Mills PLLC

(57) **ABSTRACT**

A system for treating valvular regurgitation in a heart valve includes a flexible canopy and an elongated tether including an elastic portion and an inelastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is coupled to an annulus of the heart valve and a distal end of the elongated tether is coupled to a ventricle. The flexible canopy is configured to overlay a first native leaflet of the heart valve, and tension on the elongated tether is applied and/or adjusted to prevent the first leaflet from prolapsing, to maximize coaptation of the flexible canopy with a second native leaflet of the heart valve, and to minimize regurgitation of the heart valve.

20 Claims, 17 Drawing Sheets



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2017/0189013	A1	7/2017	Morris et al.
2017/0202554	A1	7/2017	Eidenschink

* cited by examiner

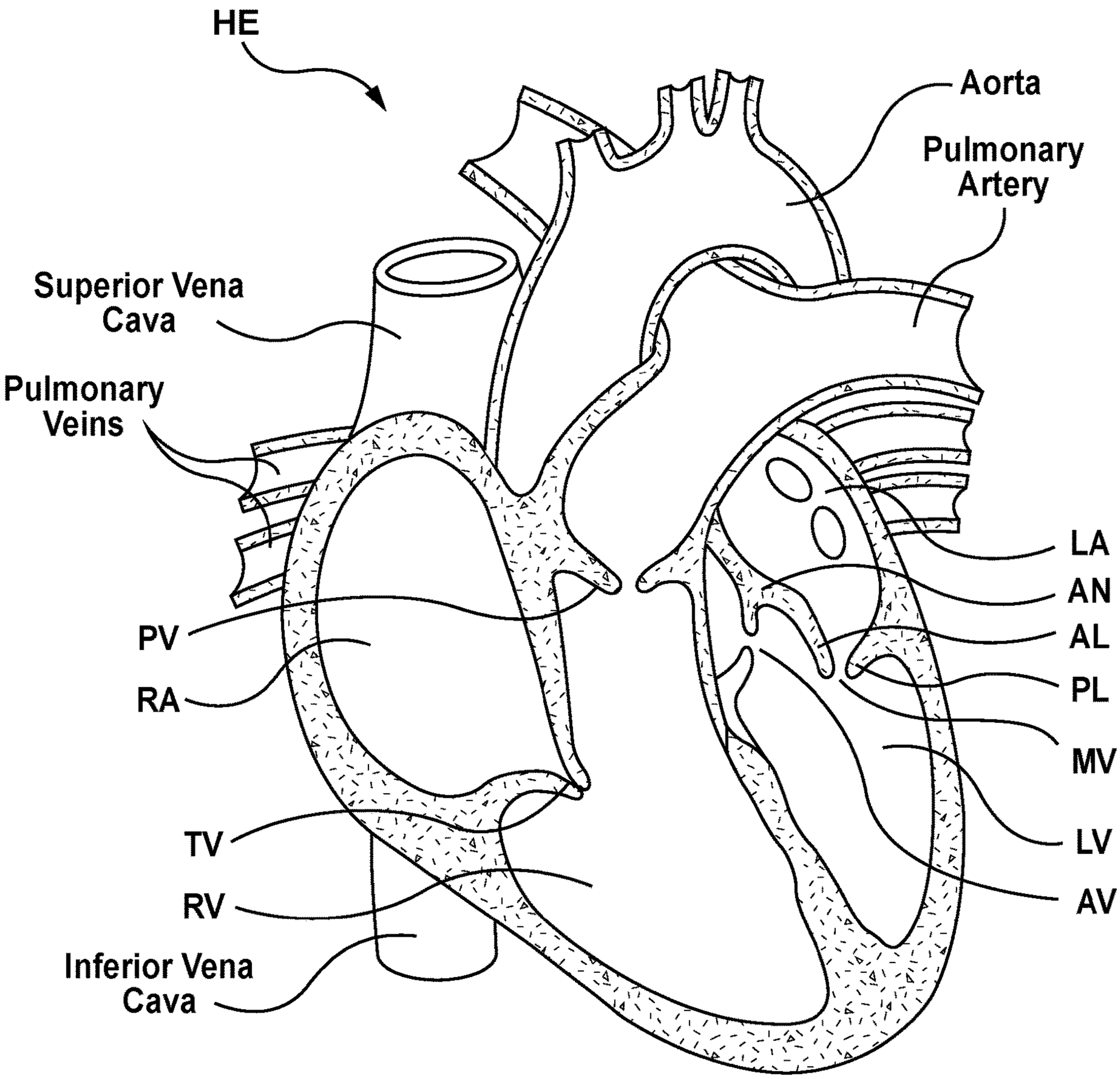

HE
Aorta
Pulmonary Artery
Superior Vena Cava
Pulmonary Veins
PV
RA
TV
RV
Inferior Vena Cava
LA
AN
AL
PL
MV
LV
AV

FIG. 1

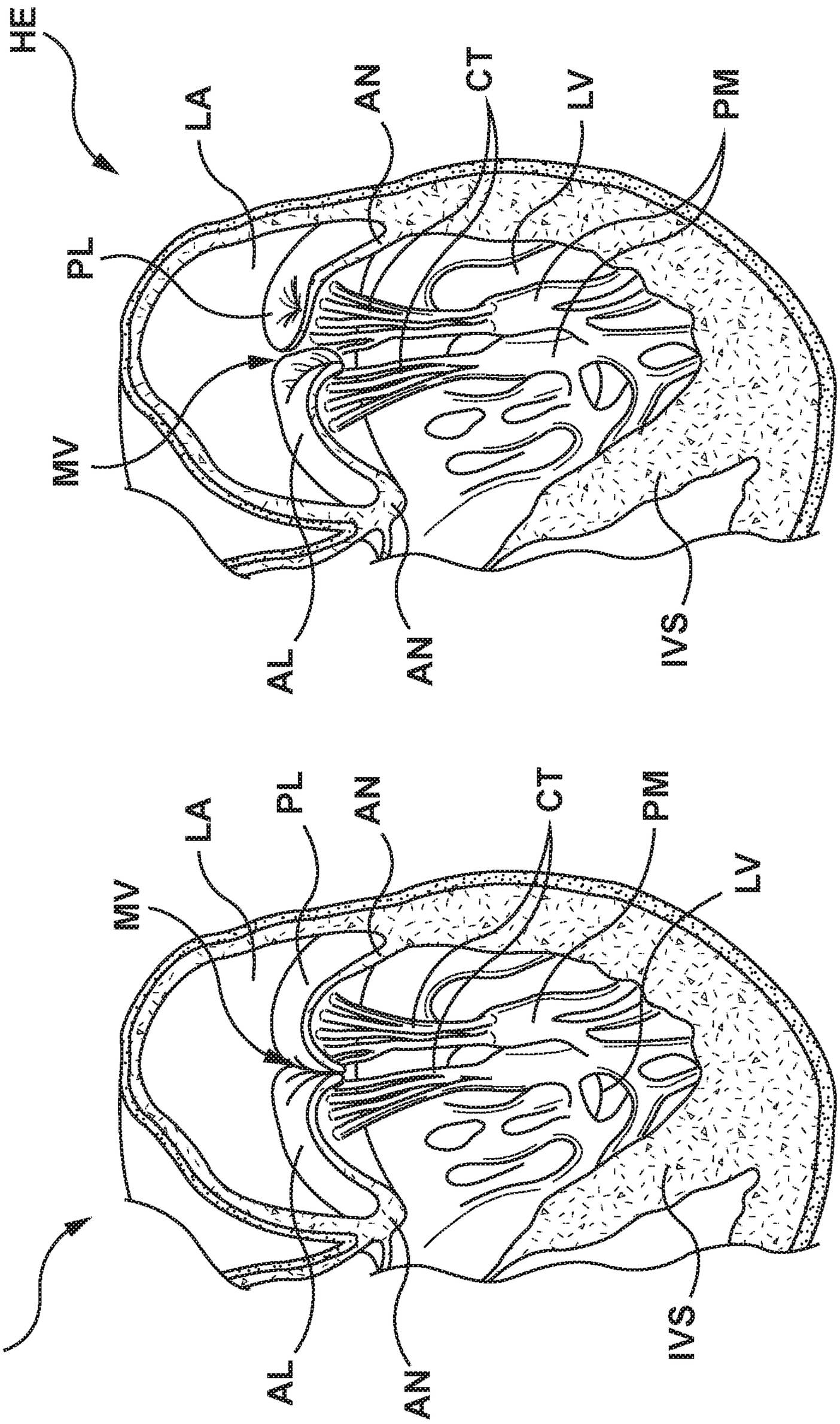


FIG. 2B

FIG. 2A

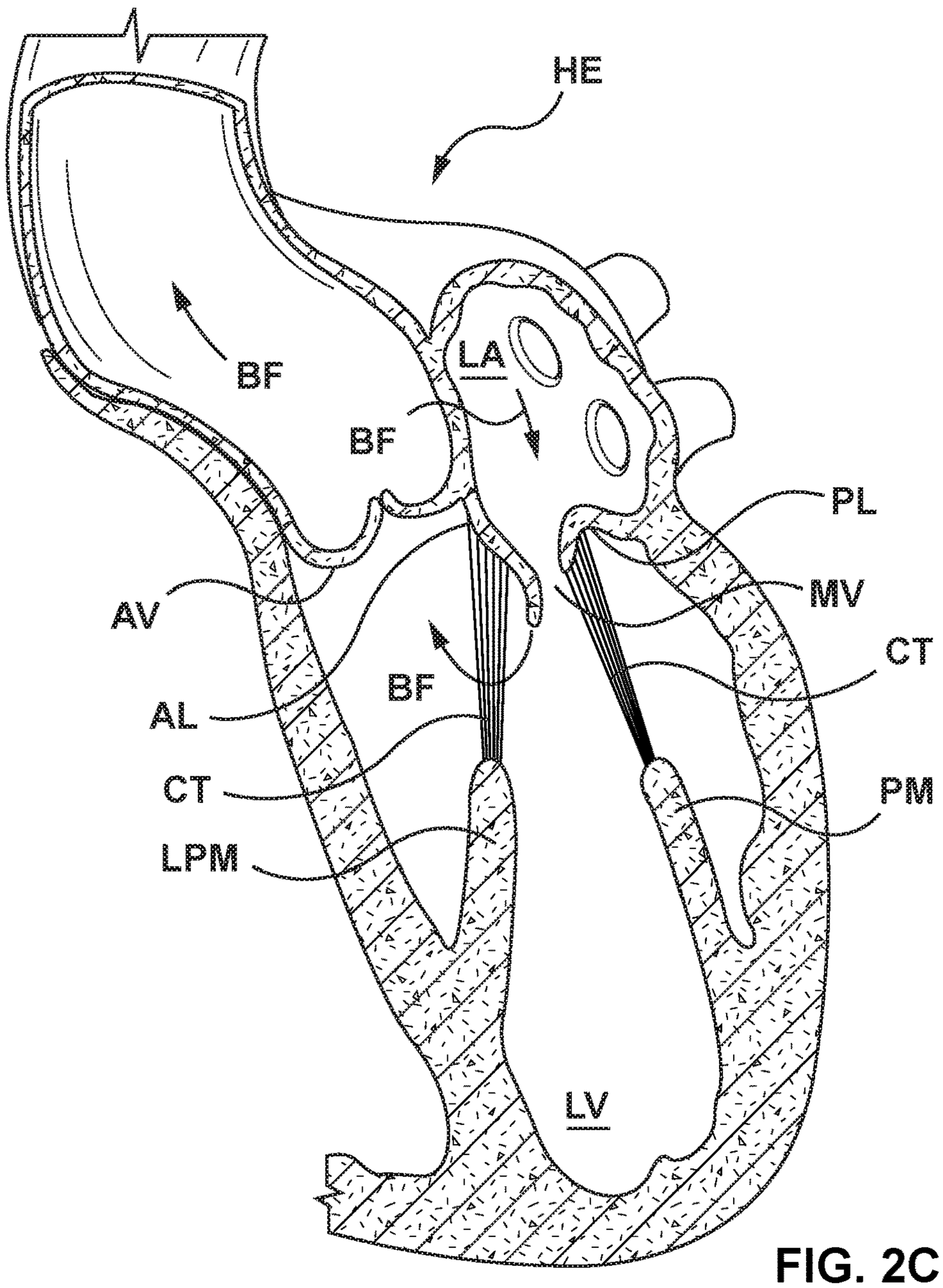


FIG. 2C

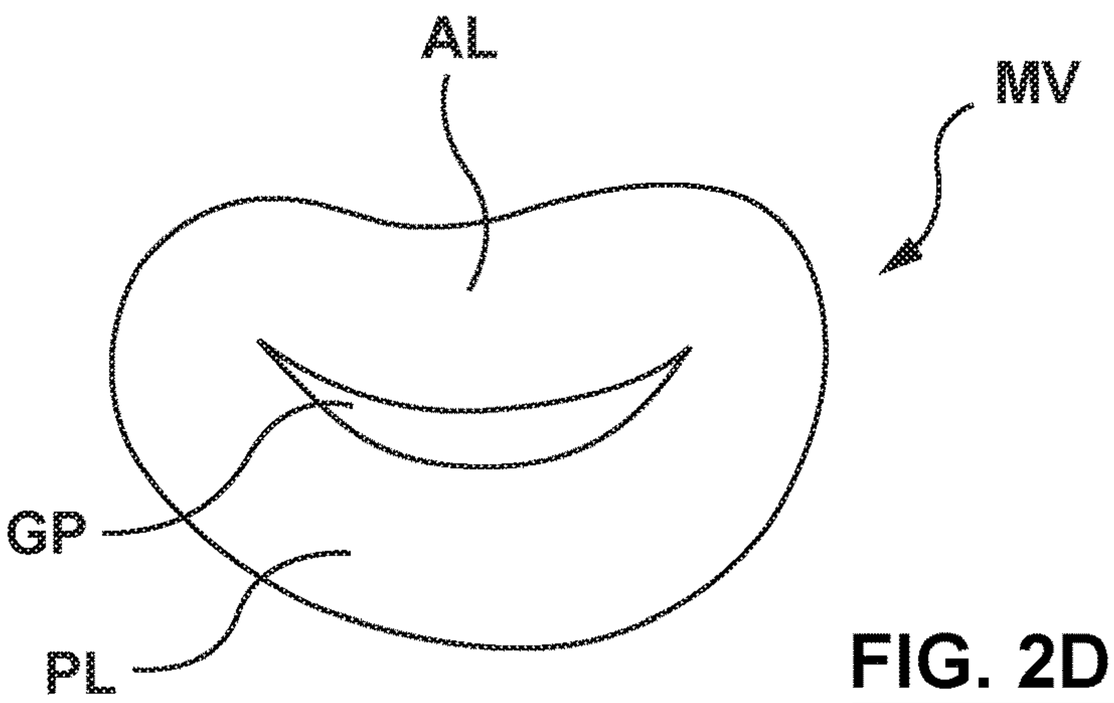


FIG. 2D

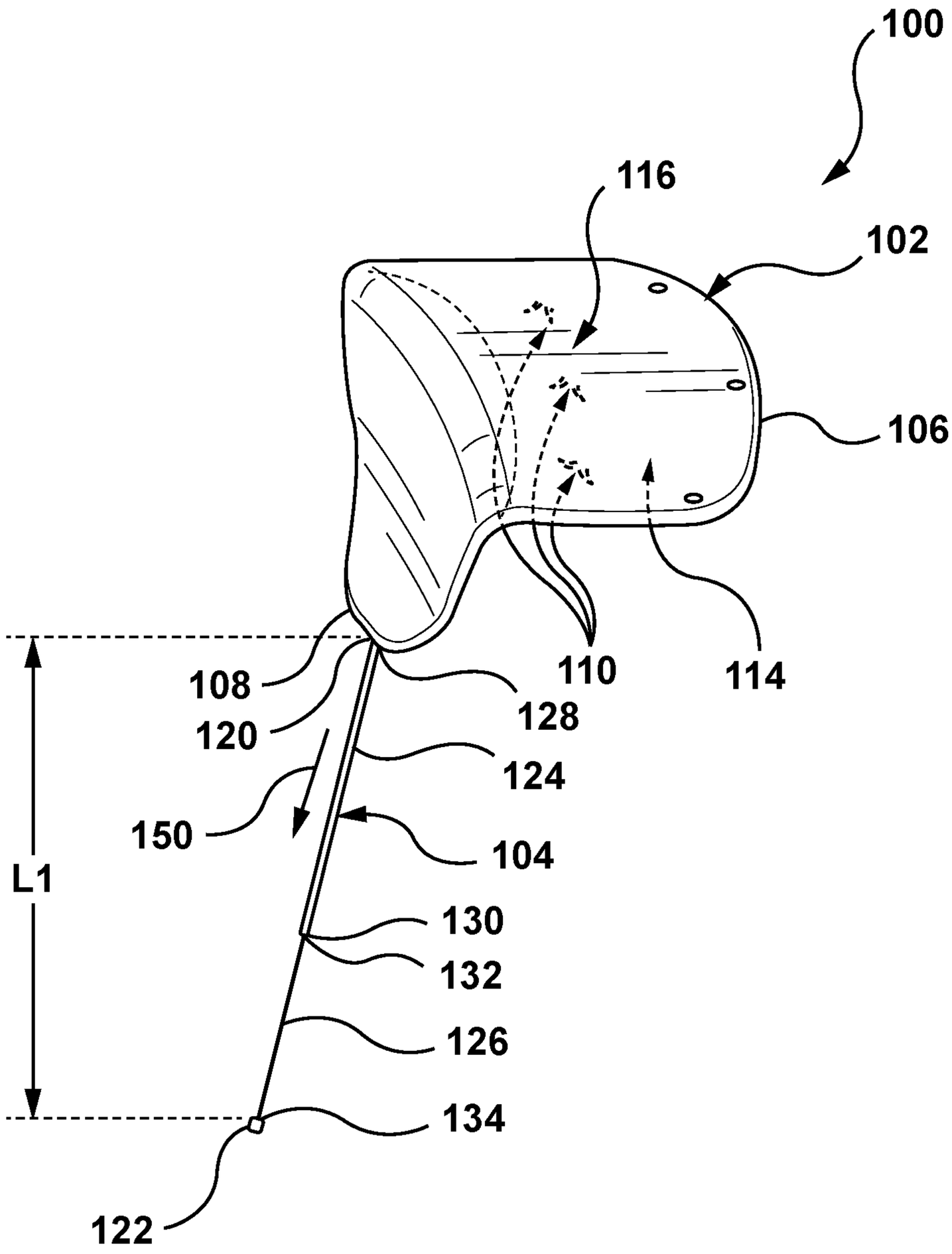

100
116
102
106
108
120
110
114
128
124
150
104
L1
130
132
126
134
122

FIG. 3A

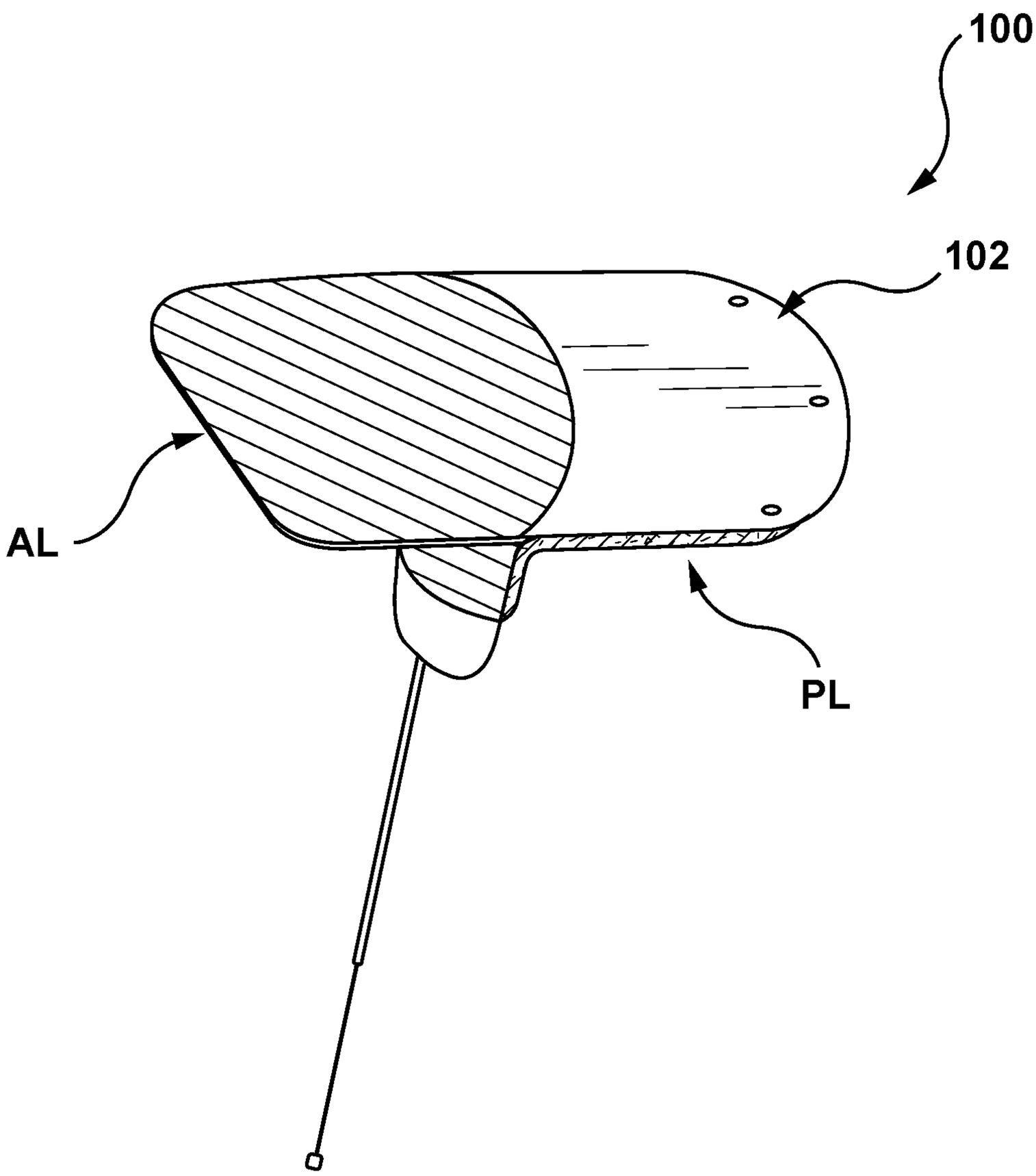
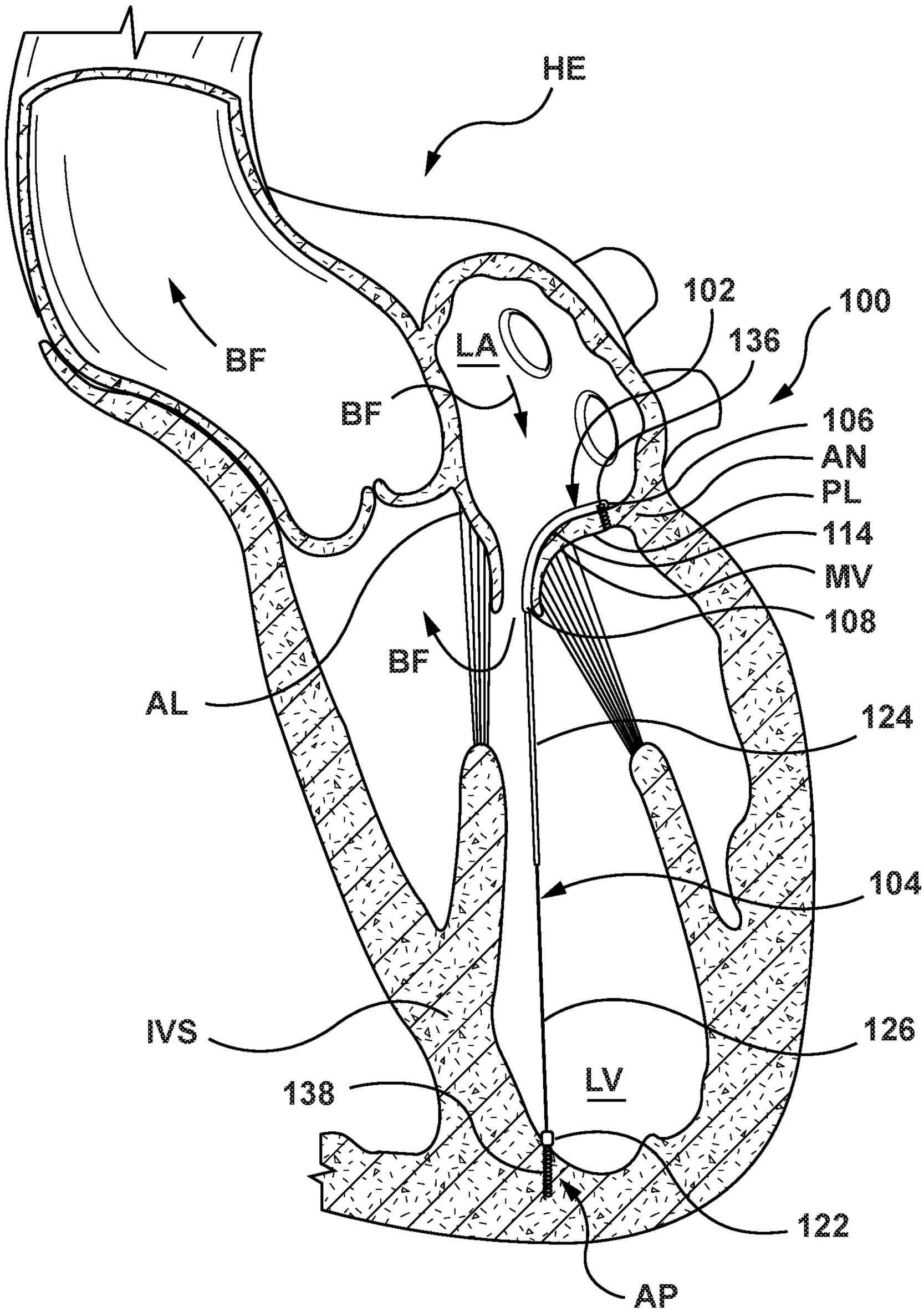


FIG. 3B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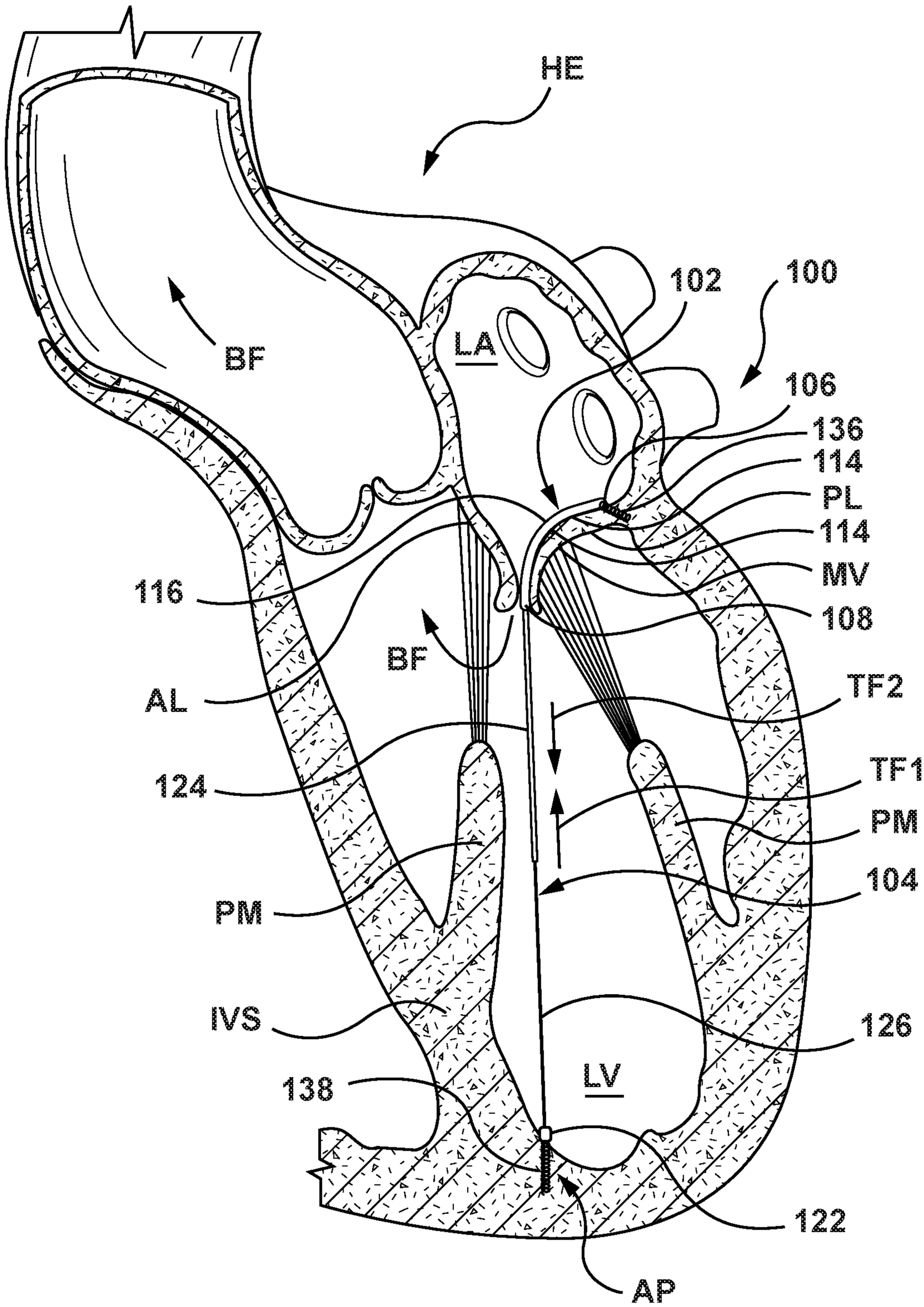
BF
LA
BF
BF
AL
IVS
138
LV
AP
102
100
136
106
AN
PL
114
MV
108
124
104
126
122

FIG. 4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BF
LA
102
100
106
136
114
PL
114
MV
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116
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AL
TF2
124
TF1
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PM
104
IVS
126
138
LV
122
AP

FIG. 5

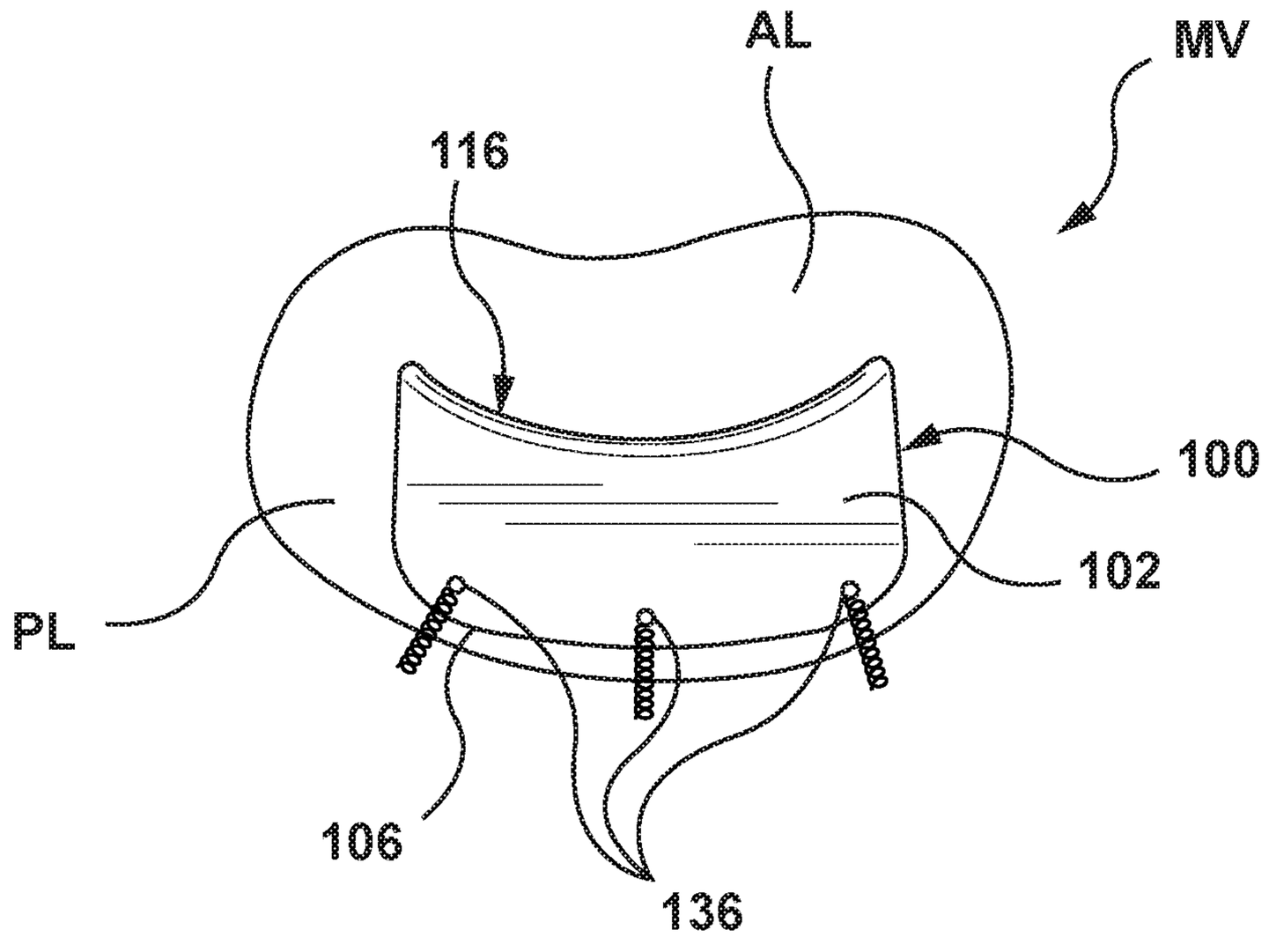
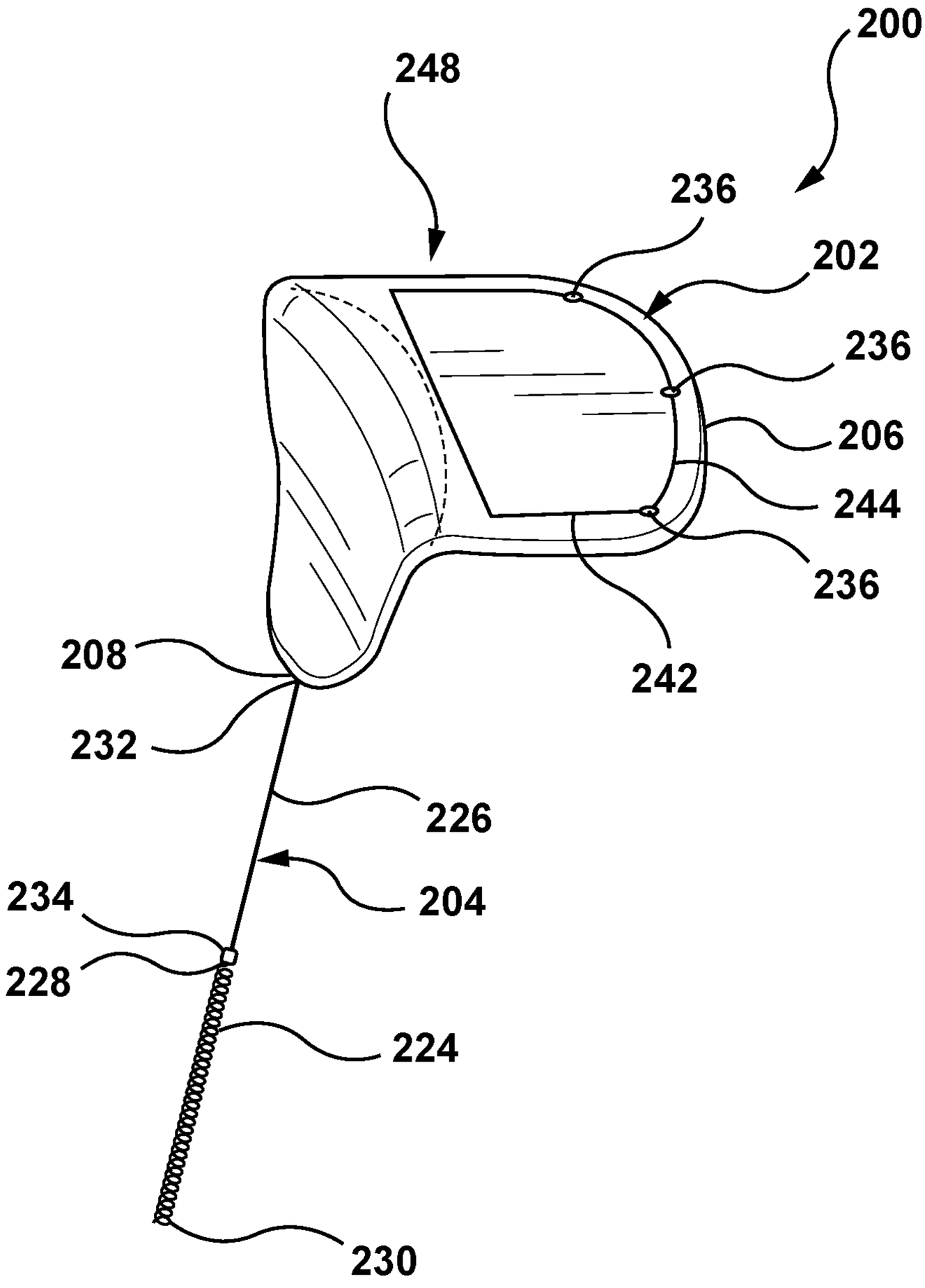


FIG. 6


200
248
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202
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206
244
236
242
208
232
226
204
234
228
224
230

FIG. 7A

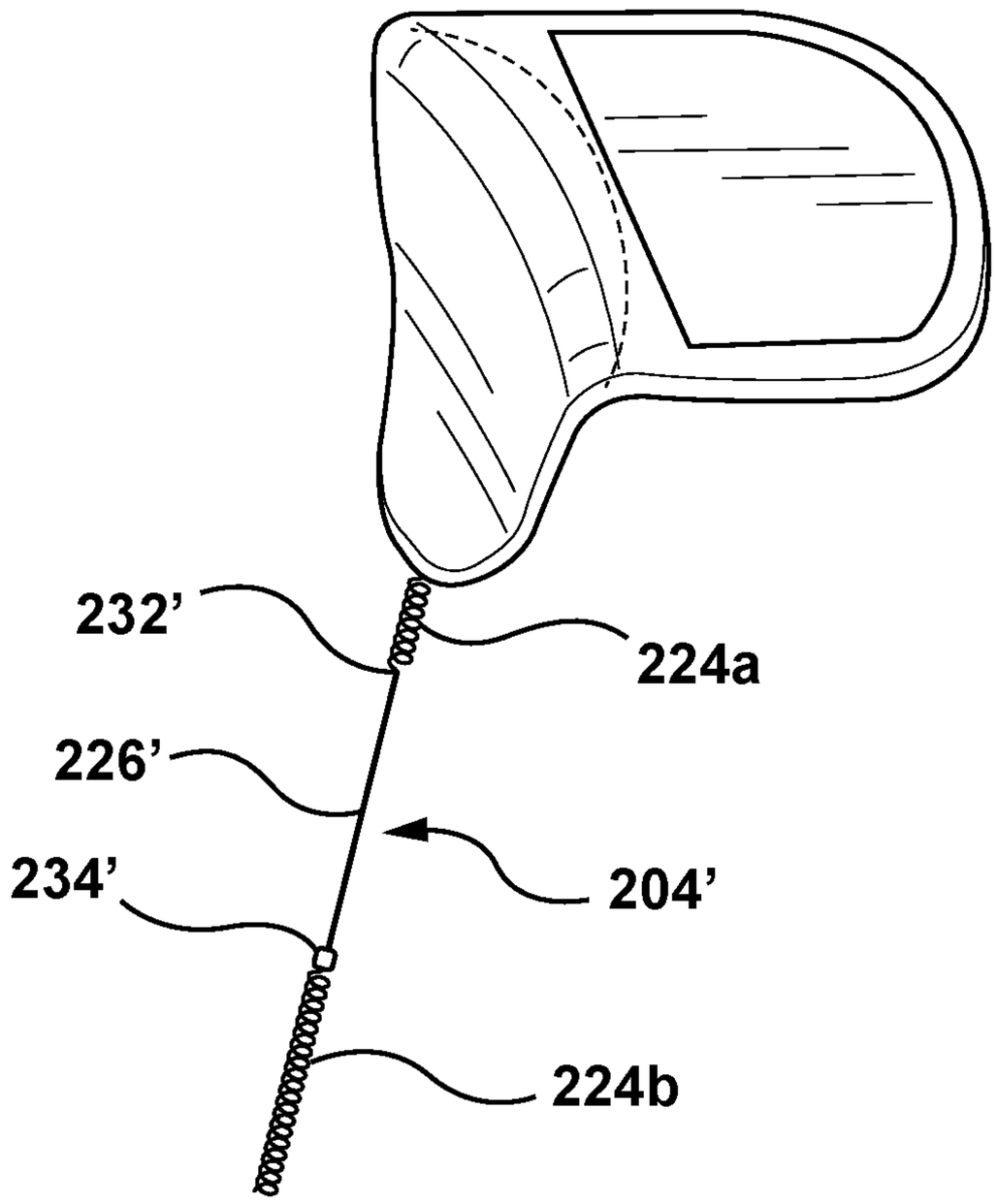

FIG. 7B

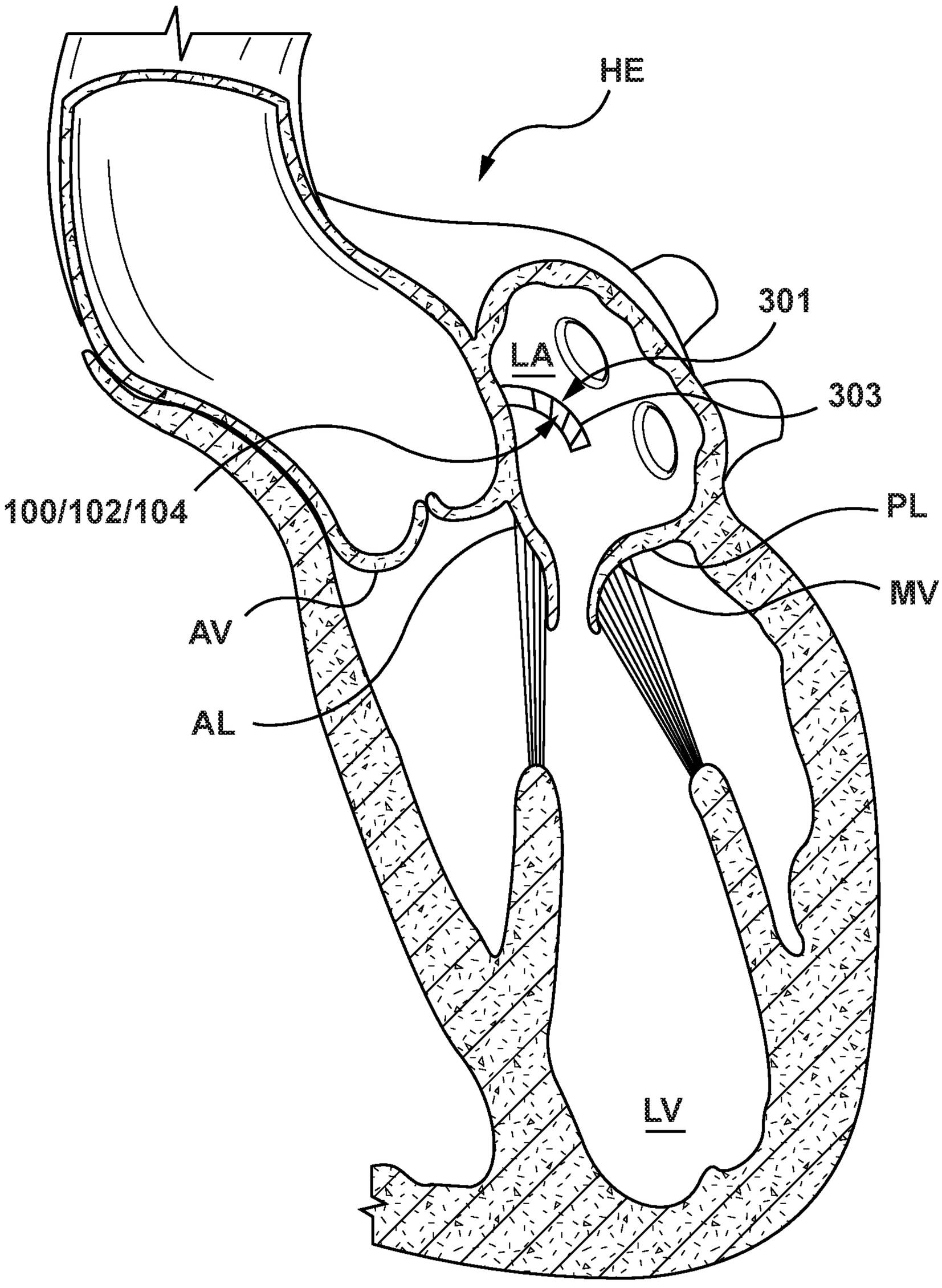

FIG. 8

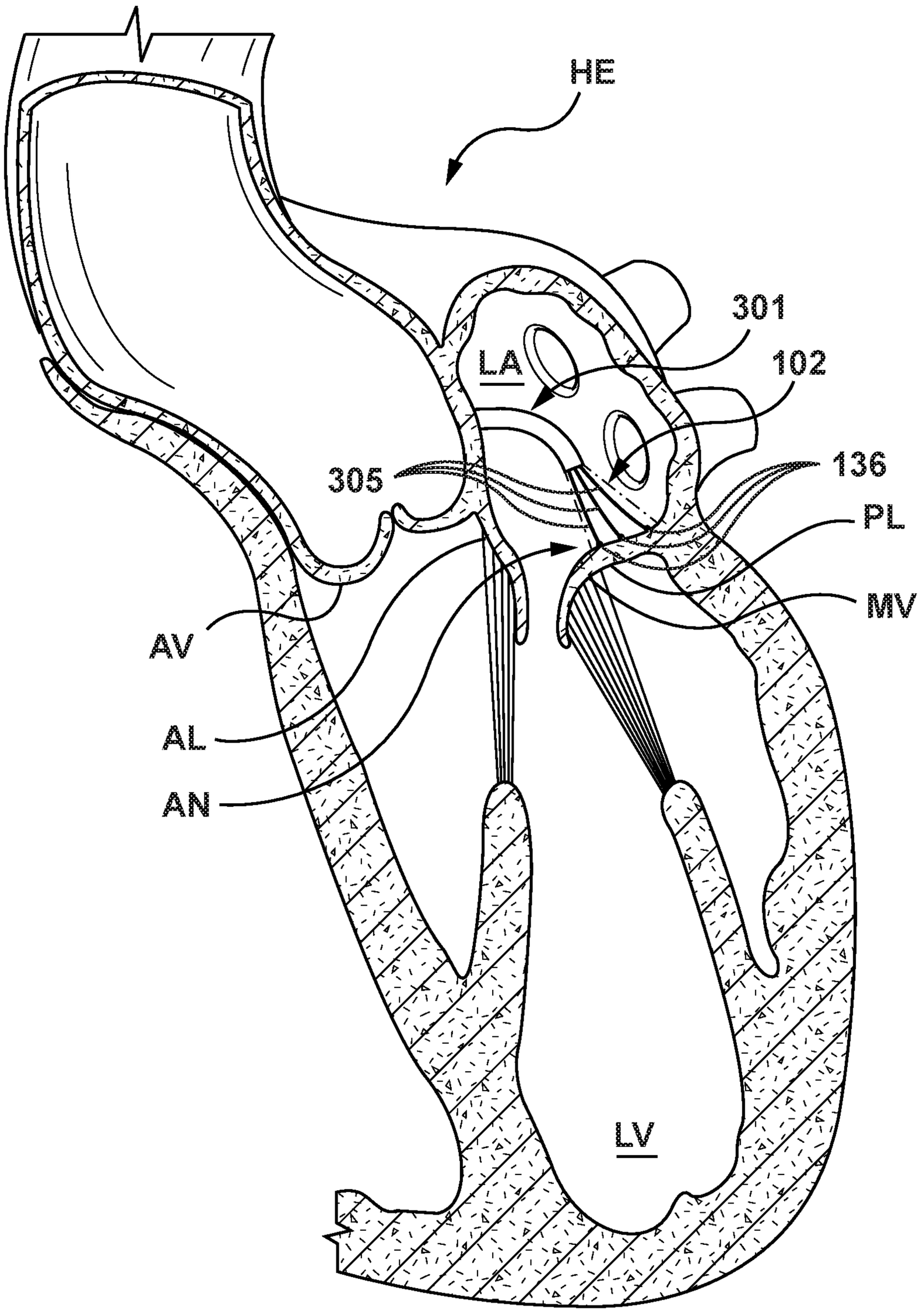

FIG. 9

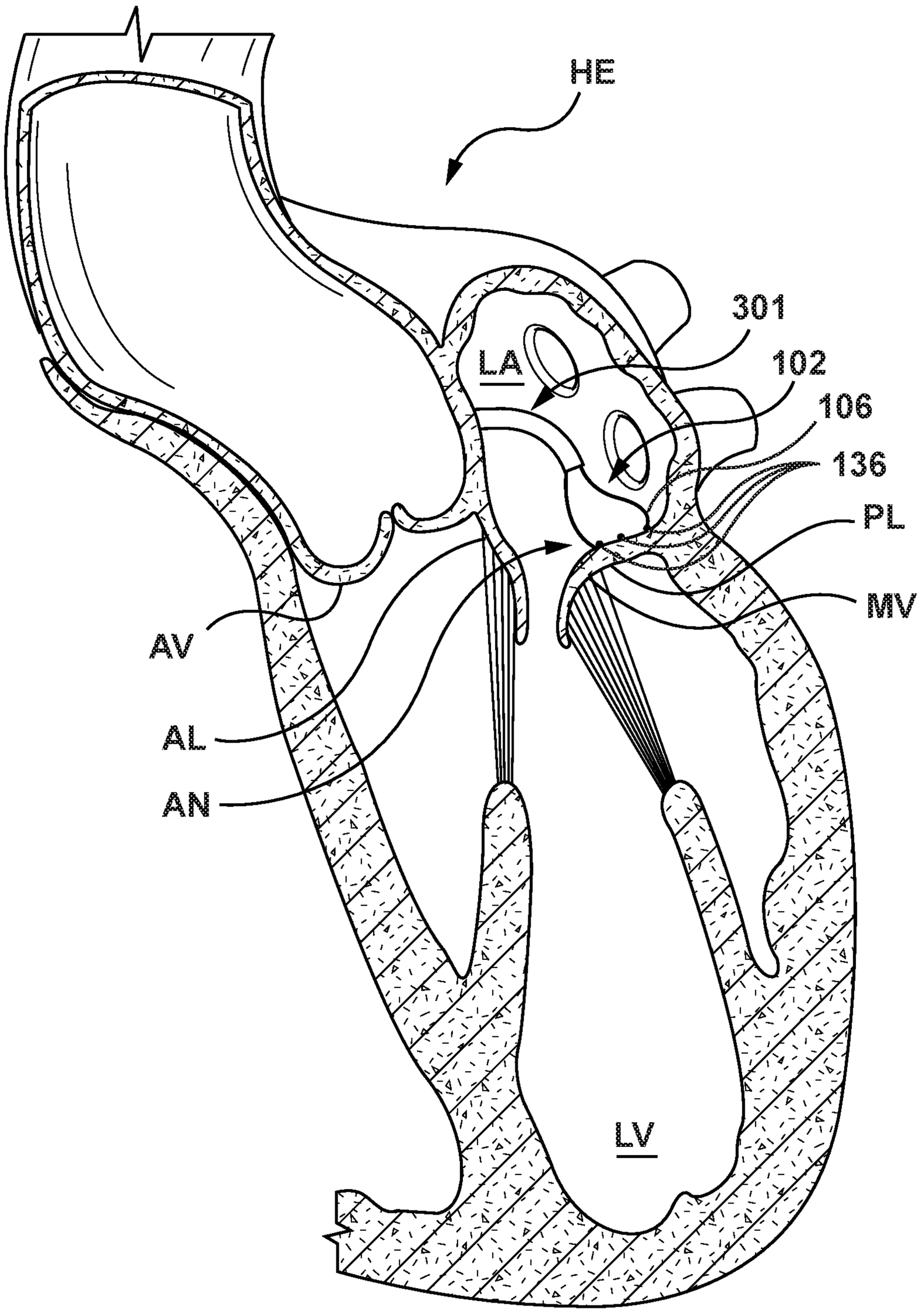

FIG. 10

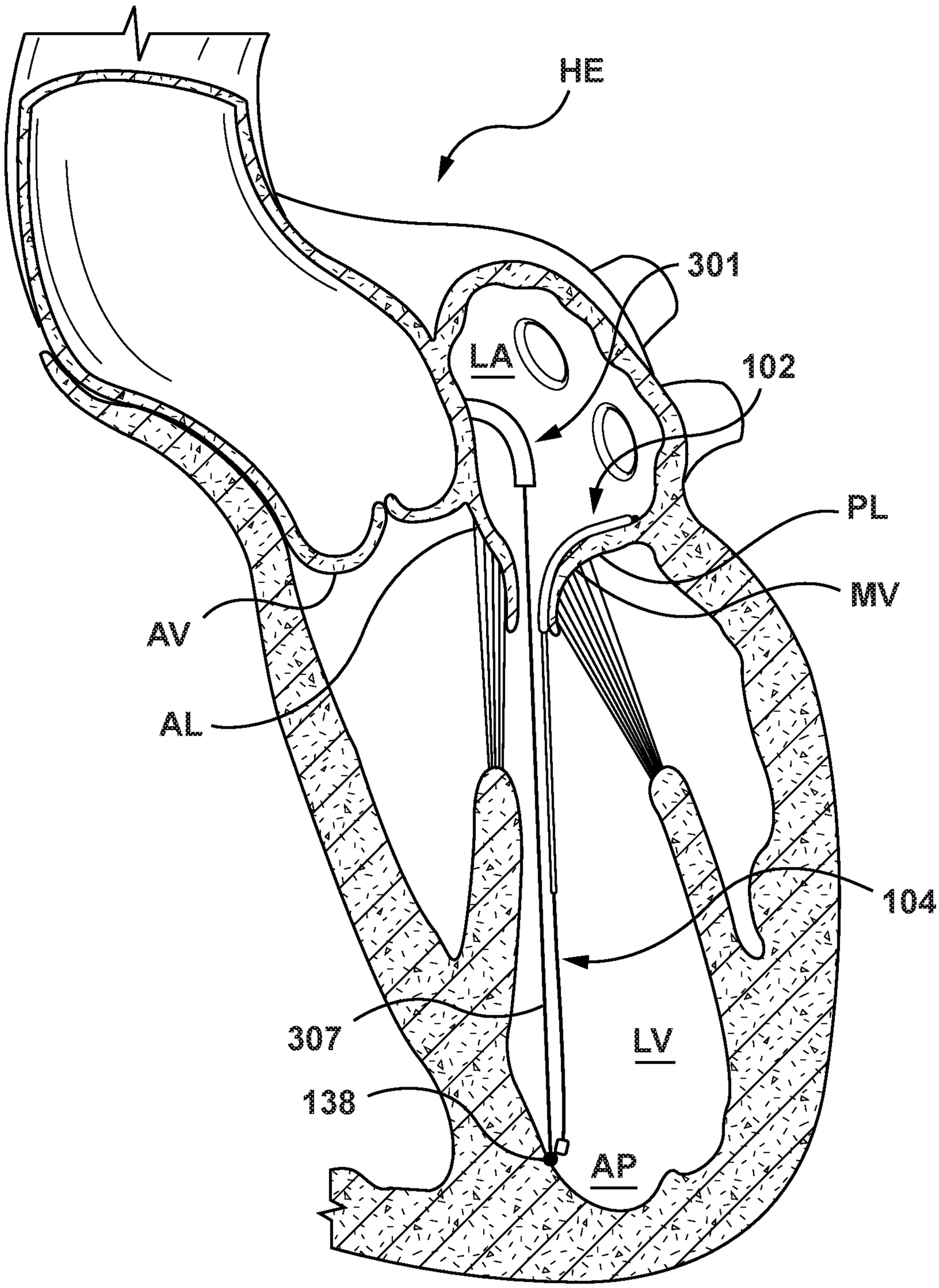

FIG. 11

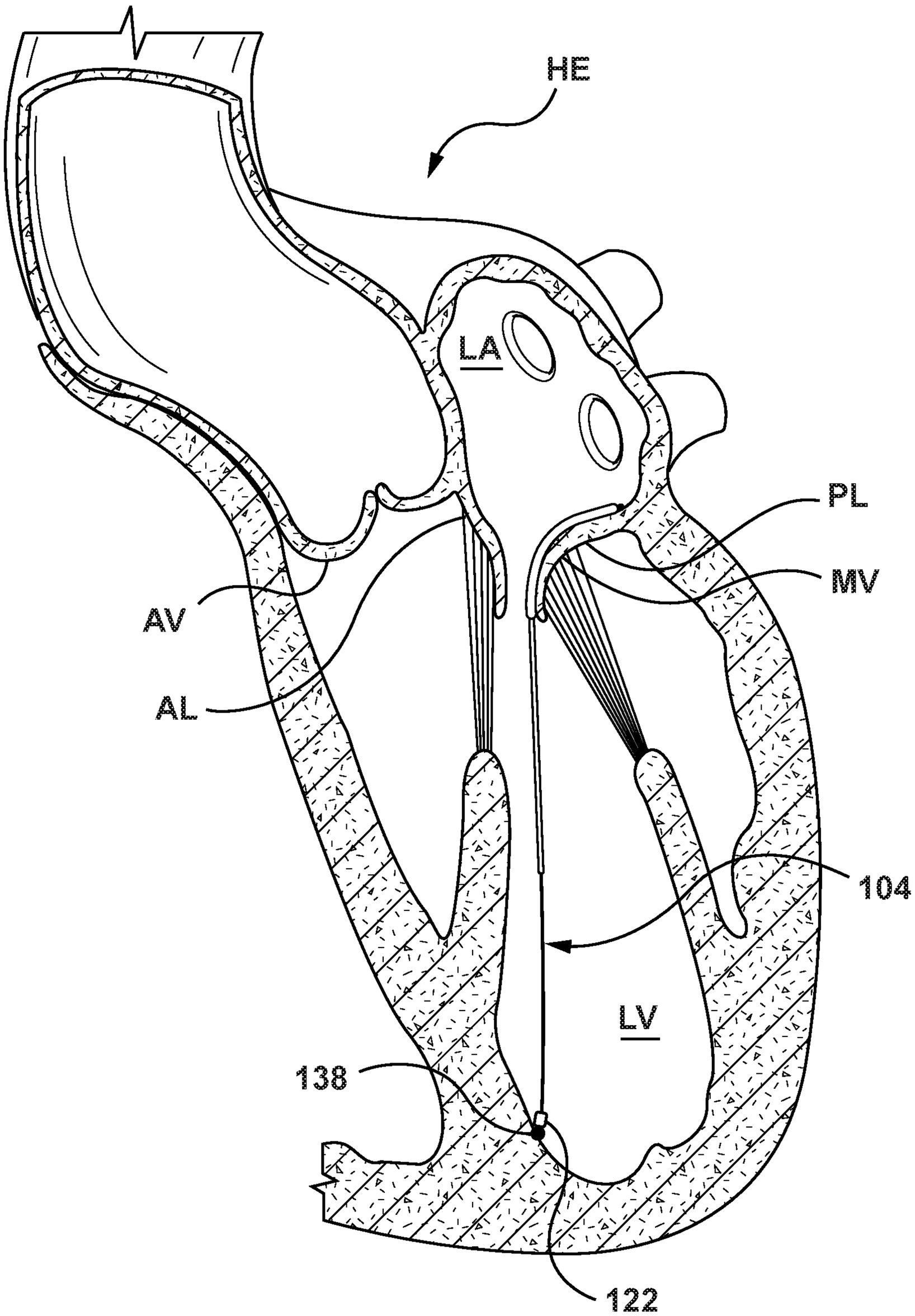

FIG. 12

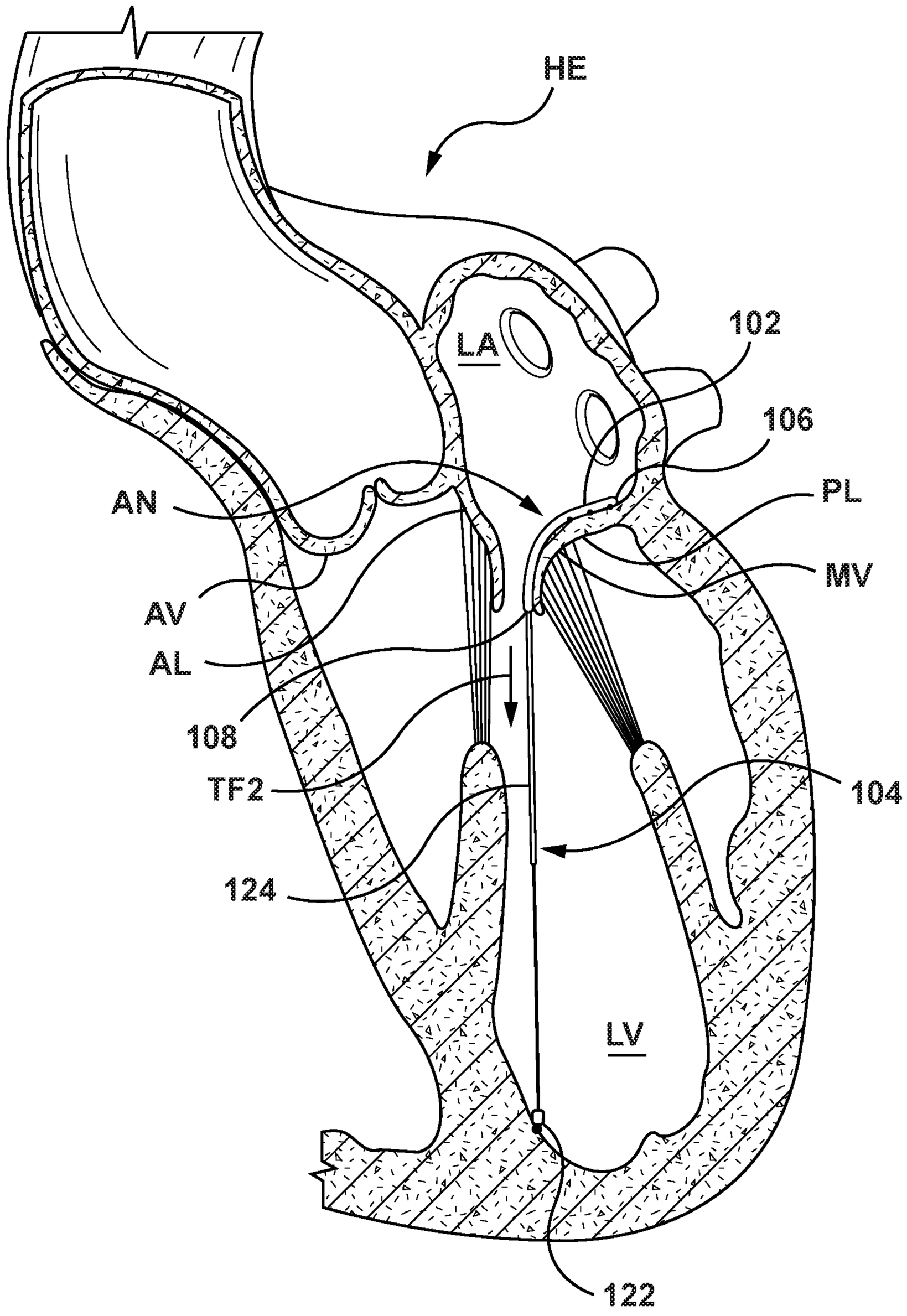

FIG. 13

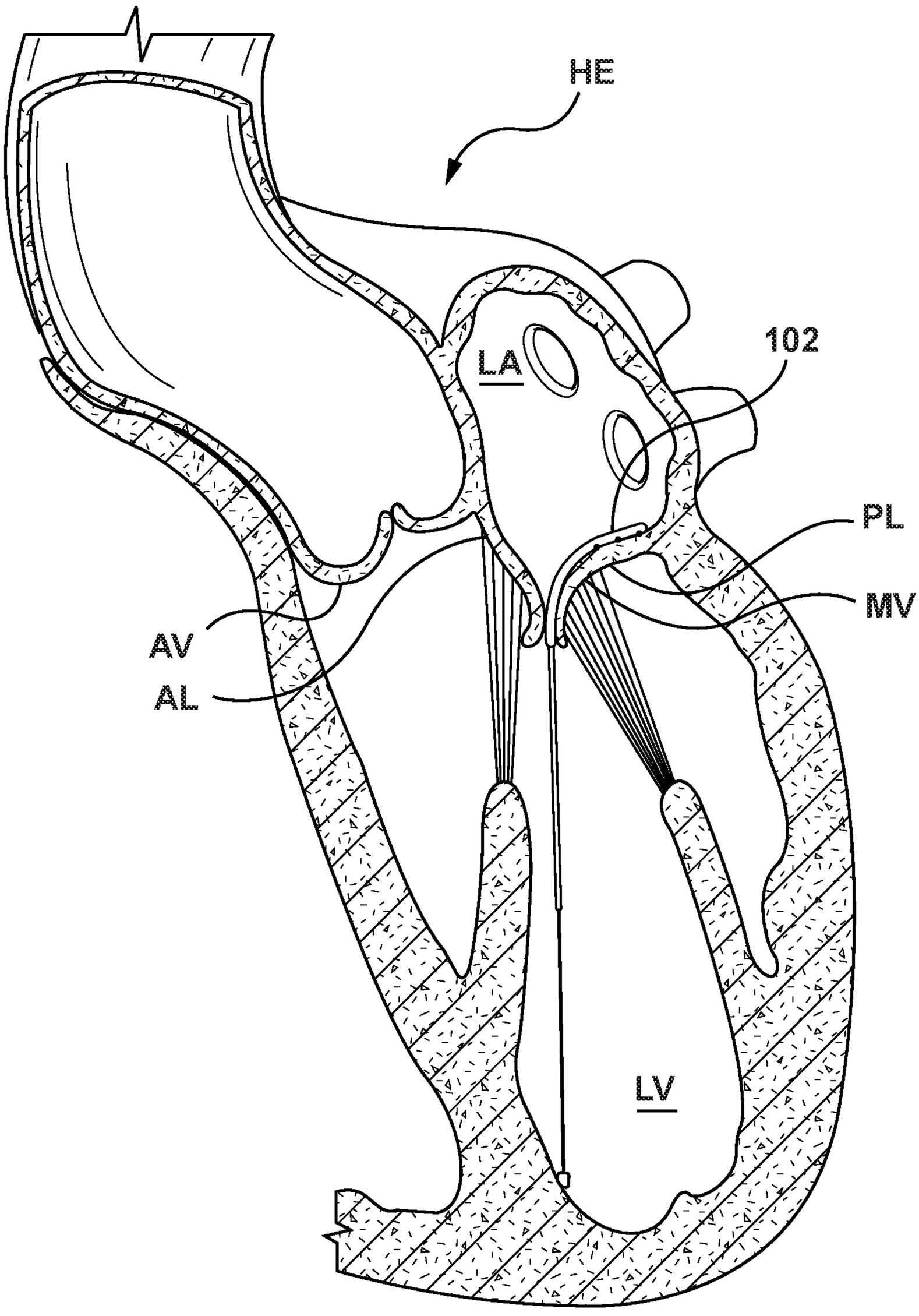

FIG. 14

FLEXIBLE CANOPY VALVE REPAIR SYSTEMS AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/645,306, filed Mar. 20, 2018, which is hereby incorporated by reference in its entirety for all purposes.

FIELD OF THE INVENTION

The present technology relates generally to a system for repairing a valve suffering from regurgitation, and associated systems and methods.

BACKGROUND OF THE INVENTION

The human heart is a four chambered, muscular organ that provides blood circulation through the body during a cardiac cycle. The four main chambers include the right atrium and right ventricle which supplies the pulmonary circulation, and the left atrium and left ventricle which supplies oxygenated blood received from the lungs to the remaining body. To ensure that blood flows in one direction through the heart, atrioventricular valves (tricuspid and mitral valves) are present between the junctions of the atrium and the ventricles, and semi-lunar valves (pulmonary valve and aortic valve) govern the exits of the ventricles leading to the lungs and the rest of the body. These valves contain leaflets or cusps that open and shut in response to blood pressure changes caused by the contraction and relaxation of the heart chambers. The leaflets move apart from each other to open and allow blood to flow downstream of the valve, and coapt to close and prevent backflow or regurgitation in an upstream manner.

The mitral valve, also known as the bicuspid or left atrioventricular valve, is a dual flap valve located between the left atrium and the left ventricle. The mitral valve serves to direct oxygenated blood from the lungs through the left side of the heart and into the aorta for distribution to the body. As with other valves of the heart, the mitral valve is a passive structure in that does not itself expend any energy and does not perform any active contractile function. The mitral valve includes two moveable leaflets, an anterior leaflet and a posterior leaflet, that each open and close in response to differential pressures on either side of the valve. Ideally, the leaflets move apart from each other when the valve is in an open configuration, and meet or "coapt" when the valve is in a closed configuration.

Diseases associated with heart valves, such as those caused by damage or a defect, can include stenosis and valvular insufficiency or regurgitation. These diseases can occur individually or concomitantly in the same valve. Valvular insufficiency or regurgitation occurs when the valve does not close completely, allowing blood to flow backwards, thereby causing the heart to be less efficient. A diseased or damaged valve, which can be congenital, age-related, drug-induced, or in some instances, caused by infection, can result in an enlarged, thickened heart that loses elasticity and efficiency. Some symptoms of heart valve diseases can include weakness, shortness of breath, dizziness, fainting, palpitations, anemia and edema, and blood clots which can increase the likelihood of stroke or pulmonary embolism. Symptoms can often be severe enough to be debilitating and/or life threatening.

In particular, a large portion or percentage of degenerative regurgitation in a mitral valve is caused by a prolapsed posterior mitral leaflet. This can be caused by weakening or separation of the chordae attached to the posterior leaflet. In such cases, when the mitral valve is in the closed configuration, the posterior mitral leaflet billows or bulges like a sail or a parachute into the left atrium, causing the posterior leaflet to not fully coapt with the anterior mitral leaflet.

Currently, treatment options for the repair of a prolapsing leaflet includes re-sectioning of the prolapsed tissue, chordae repair, foldoplasty, annuloplasty, placement of a new valve, or attachment of a clip to couple a free end of the prolapsing leaflet to a free end of a non-prolapsing leaflet. However, these solutions have significant drawbacks in terms of efficacy, safety or likelihood of complications, invasiveness, reduction in the cross-sectional area for blood flow through the valve, and the availability of the valve for future treatments.

Accordingly, there is a need for systems that can repair a valve suffering from regurgitation due to a prolapsing leaflet more easily, with greater efficacy and fewer complications. Further, there is a need for systems that can repair a valve suffering from regurgitation due to a prolapsing leaflet while leaving the valve available for future treatments.

BRIEF SUMMARY OF THE INVENTION

Embodiments hereof are directed to a system for treating a valvular regurgitation in a heart valve. The system includes a flexible canopy and an elongated tether. A proximal end of the elongated tether is attached to a distal end of the flexible canopy. The flexible canopy includes a first surface and a second surface opposite the first surface. The elongated tether is configured to be placed under tension in situ and includes an inelastic portion and an elastic portion that is at least as long as the inelastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of a heart valve and a distal end of the elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

In another embodiment hereof, the system includes a flexible canopy and an elongated tether. A proximal end of the elongated tether is attached to a distal end of the flexible canopy. The flexible canopy includes a first surface and a second surface opposite the first surface. The flexible canopy is unsupported and does not include a frame attached thereto. The elongated tether is configured to be placed under tension in situ and includes an inelastic portion and an elastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of a heart valve and a distal end of the elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

Embodiments hereof are further directed to a method of treating a valvular regurgitation. The method includes percutaneously delivering a system in a delivery configuration to a heart valve. The system includes a flexible canopy and an elongated tether attached to a distal end of the flexible canopy. The flexible canopy is unsupported and does not include a frame coupled thereto and the elongated tether includes an inelastic portion and an elastic portion that is at least as long as the inelastic portion. At least one proximal anchor is embedded into an annulus of the heart valve. A proximal end of the flexible canopy is coupled to the at least one proximal anchor. A distal anchor is embedded into a ventricle adjacent to the heart valve. A distal end of the elongated tether is coupled to the distal anchor. A tension force is applied on the flexible canopy such that a first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The heart valve is checked for regurgitation. The tension force on the flexible canopy is adjusted to minimize valvular regurgitation.

BRIEF DESCRIPTION OF DRAWINGS

The foregoing and other features and aspects of the present technology can be better understood from the following description of embodiments and as illustrated in the accompanying drawings. The accompanying drawings, which are incorporated herein and form a part of the specification, further serve to illustrate the principles of the present technology. The components in the drawings are not necessarily to scale.

FIG. **1** is a schematic sectional illustration of a mammalian heart having native valve structures.

FIG. **2**A is a schematic sectional illustration of a left ventricle of a mammalian heart showing anatomical structures and a native mitral valve.

FIG. **2**B is a schematic sectional illustration of the left ventricle of a heart having a prolapsed mitral valve in which the leaflets do not sufficiently coapt and which is suitable for repair with a system in accordance with embodiments hereof.

FIG. **2**C is a schematic sectional illustration of the left ventricle of FIG. **2**B as viewed from a different angle.

FIG. **2**D is a top view illustration of the prolapsed mitral valve of FIG. **2**B, wherein the mitral valve is in an open configuration.

FIG. **3**A is a perspective illustration of a system for treating heart valvular regurgitation in accordance with an embodiment hereof.

FIG. **3**B is a perspective illustration of the system of FIG. **3**A and an anterior leaflet of a native mitral valve.

FIG. **4** is a schematic sectional illustration of a heart, wherein the system of FIG. **3**A is implanted within the heart in a deployed configuration and a native mitral valve of the heart is in the open configuration.

FIG. **5** is a schematic sectional illustration of the heart, wherein the system of FIG. **3**A is implanted within the heart in a deployed configuration and the native mitral valve of the heart in a closed configuration.

FIG. **6** is a top view illustration of the mitral valve of FIG. **5**, wherein the mitral valve is in the closed configuration.

FIG. **7**A is a perspective illustration of a system for treating heart valvular regurgitation in accordance with another embodiment hereof.

FIG. **7**B is a perspective illustration of a system for treating heart valvular regurgitation in accordance with yet another embodiment hereof.

FIG. **8** is a sectional cut-away illustration of a heart illustrating a method step of using the system of FIG. **3**A to repair a prolapsed posterior leaflet of a native mitral valve using a transseptal approach in accordance with an embodiment hereof, wherein the system of FIG. **3**A is shown in the delivery configuration within a delivery catheter positioned within the left atrium of the heart.

FIG. **9** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a plurality of proximal anchors is deployed to engage tissue at the annulus of the native mitral valve.

FIG. **10** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a proximal end of a flexible canopy of the system is coupled to the plurality of proximal anchors at the annulus of the native mitral valve.

FIG. **11** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a distal anchor is deployed to engage tissue in a left ventricle of the heart.

FIG. **12** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a distal end of an elongated tether of the system is coupled to the distal anchor in the left ventricle.

FIG. **13** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a tension of the elongated member is applied such that the flexible canopy overlays the posterior leaflet of the native mitral valve.

FIG. **14** is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. **3**A to repair the prolapsed posterior leaflet of the mitral valve, wherein the tension of the elongated tether is adjusted to minimize regurgitation at the mitral valve.

DETAILED DESCRIPTION OF THE INVENTION

Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms "distal" and "proximal", when used in the following description to refer to a delivery device, delivery system, or delivery catheter are with respect to a position or direction relative to the treating clinician. Thus, "distal" and "distally" refer to positions distant from, or in a direction away from the treating clinician, and the terms "proximal" and "proximally" refer to positions near, or in a direction toward the clinician. The terms "distal" and "proximal", when used in the following description to refer to a system or a device to be implanted into a vessel, such as a system for treating heart valvular regurgitation, are used with reference to the direction of blood flow. Thus, "distal" and "distally" refer to positions in a downstream direction with respect to the direction of blood flow, and the terms "proximal" and "proximally" refer to positions in an upstream direction with respect to the direction of blood flow.

The following detailed description is merely exemplary in nature and is not intended to limit the present technology or the application and uses of the present technology. Although the description of embodiments hereof is in the context of treatment of heart valvular regurgitation and particularly in

the context of treatment of regurgitation of the mitral valve, the present technology may also be used in any other body passageways where it is deemed useful. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

FIGS. **1**-**2**D will now be described to provide contextual information on valve regurgitation. FIG. **1** is a schematic sectional illustration of a mammalian heart HE that depicts the four heart chambers (right atrium RA, right ventricle RV, left atrium LA, left ventricle LV) and native valve structures (tricuspid valve TV, mitral valve MV, pulmonary valve PV, aortic valve AV). FIG. **2**A is a schematic sectional illustration of a left ventricle LV of a mammalian heart HE showing anatomical structures and a native mitral valve MV. Referring to FIGS. **1** and **2**A together, the heart HE comprises the left atrium LA that receives oxygenated blood from the lungs via the pulmonary veins. The left atrium LA pumps the oxygenated blood through the mitral valve MV and into the left ventricle LV during ventricular diastole. The left ventricle LV contracts during systole and blood flows outwardly through the aortic valve AV, into the aorta and to the remainder of the body.

In a healthy heart, the mitral valve MV includes an open configuration and a closed configuration. When the mitral valve MV is in the open configuration, an anterior leaflet AL and a posterior leaflet PL do not coapt, permitting blood to flow from the right atrium RA to the left ventricle LV. When the mitral valve is in the closed configuration, as shown in FIG. **2**A, the anterior and posterior leaflets AL, PL of the native mitral valve MV meet evenly at the free edges or "coapt" to close and prevent back flow of blood into the left atrium LA during contraction of the left ventricle LV. The tissue of the anterior and posterior leaflets AL, PL attach to the surrounding heart structure via a dense fibrous ring of connective tissue called an annulus AN which is distinct from both the tissue of the anterior and posterior leaflets AL, PL as well as the adjoining muscular tissue of the heart wall. In general, the connective tissue at the annulus AN is more fibrous, tougher and stronger than leaflet tissue. The flexible tissue of the anterior and posterior leaflets AL, PL of the native mitral valve MV are connected to papillary muscles PM, which extend upwardly from the lower wall of the left ventricle LV and the interventricular septum IVS, via branching tendons called chordae tendinae CT.

In a heart HE having a mitral valve MV experiencing valvular regurgitation due to a prolapsing first or posterior leaflet PL and a second or anterior leaflet AL, the respective edges of the posterior leaflet PL and the anterior leaflet AL do not sufficiently coapt or meet, as shown in FIGS. **2**B-**2**D and leakage from the left ventricle LV into the left atrium LA will occur through a gap GP. Several structural defects can cause the mitral leaflets LF to prolapse, and subsequent regurgitation to occur, including ruptured chordae tendinae CT, impairment of papillary muscles PM (e.g., due to ischemic heart disease), and enlargement of the heart and/or mitral valve annulus AN (e.g., cardiomyopathy).

Embodiments of systems and associated methods in accordance with the present technology are described with reference to FIGS. **3**A-**14**. It will be appreciated that specific elements, substructures, uses, advantages, and/or other aspects of the embodiments described herein and with reference to FIGS. **3**A-**14** can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology.

Provided herein are systems and methods suitable for repairing a prolapsing leaflet of a heart valve to reduce or eliminate valvular regurgitation. More specifically, in embodiments hereof, a flexible canopy of the system is placed over an existing native leaflet of the heart valve and tensioned with an elongated tether to prevent leaflet prolapse and subsequent regurgitation resulting from the prolapsing leaflet. The system is adjustable via the elongated tether to set the system to minimize or eliminate valvular regurgitation. Further, the system may be readjusted during the initial procedure or in a subsequent procedure or procedures to account for changes in the native anatomy over time. The systems described herein do not reduce or alter the cross-sectional area of the native mitral valve and thus reduced blood flow through the heart valve is avoided and easy access to the heart valve is still permitted for future therapies and treatments.

Turning now to FIG. **3**A, FIG. **3**A is a perspective view of a system **100** for treating valvular regurgitation in a heart valve due to a prolapsing leaflet and configured in accordance with an embodiment hereof. The system **100** includes a flexible canopy **102** and an elongated tether **104**. Further, the system **100** includes a delivery configuration, wherein the system is compressed for percutaneous delivery within a delivery catheter to a desired treatment location, and a deployed configuration, which is shown in FIG. **3**A. When the system **100** is in the delivery configuration, the flexible canopy **102** can be folded, rolled, or otherwise compressed. The method of compressing the flexible canopy **102** is selected based upon a variety of characteristics including, but not limited to the order or sequence of anchor fixation or deployment.

As shown in FIG. **3**A, the flexible canopy **102** is formed of a flexible material and includes a proximal end **106**, a distal end **108** opposite the proximal end **106**, an underside or first surface **114** and a top or second surface **116** opposite the first surface **114**. The flexible canopy **102** may be formed of materials which will bond to the prolapsing leaflet via growth such as, but not limited to Dacron®, pericardial tissue, or other suitable materials. The proximal end **106** of the flexible canopy **102** is configured to be anchored in situ at or on an annulus of the heart valve. As used herein, "at or on" an annulus means at or on a level of a plane of the annulus of the native heart valve, including disposition at or on a level of an upper surface of the annulus or other superior levels of the valve. Further, when the system **100** is in the deployed configuration, the flexible canopy **102** is configured to overlay an underlying or concealed portion of a prolapsing leaflet of the native heart valve such that the first surface **114** abuts against or contacts the underlying portion of the prolapsing leaflet, as described in more detail below. The flexible nature of the flexible canopy **102** permits the flexible canopy **102** to conform to the shape of the native prolapsing leaflet as best shown in FIG. **3**B. FIG. **3**B shows the system **100** with the flexible canopy **102** thereof overlaying and conforming to a native posterior leaflet PL, with the flexible canopy **102** coapting with a native anterior leaflet AL of a native heart valve. As used herein, the term "conform" means that the flexible canopy **102** assumes the same shape, outline, or contour of the underlying anatomy of the native prolapsing leaflet such that the flexible canopy **102** maintains consistent and close contact with the native prolapsing leaflet adjacent thereto. Thus, while the flexible canopy **102** of FIG. **3**A is shown with a particular shape, this is by way of example and not limitation, and it will be understood that the flexible canopy **102** assumes or conforms to the shape of the native prolapsing leaflet. Such

conformability is required in order for the system **100**, and more particularly the flexible canopy **102** to prevent the native leaflet from prolapsing when the system **100** is in the deployed configuration as described in greater detail below. Over time, due to the material of the flexible canopy **102**, the first surface **114** of the flexible canopy **102** bonds or fuses to the underlying first surface of the prolapsing leaflet.

In the embodiment of FIG. **3**A, the first surface **114** of the flexible canopy **102** includes a plurality of micro-tines or micro-barbs **110** configured to aid in coupling the first surface **114** of the flexible canopy **102** to the underlying first surface of the native prolapsing leaflet. While shown in FIG. **3**A with three (3) micro-barbs **110**, this is by way of example and not limitation and more or fewer micro-barbs **110** may be used. In an embodiment, the micro-barbs **110** may have a diameter in a range of between about 0.005 inches and about 0.010 inches, and the length of the micro-barbs **110** may be in a range of between about 0.010 inches and about 0.100 inches. The micro-barbs **110** may be shaped to embed into an adjacent surface such as, but not limited to, a wedged shape where the tip of the wedge comes in contact with the adjacent surface. In another embodiment, the micro-barbs **110** may be a series of metallic wires.

In the embodiment depicted in FIGS. **3**A and **3**B, the flexible canopy **102** is unsupported. Stated another way, in the embodiment depicted in FIGS. **3**A and **3**B, the flexible canopy **102** does not include a support frame and consists only of the flexible material that has the first surface **114** and the opposing second surface **116**. As used herein, "unsupported" means that the flexible canopy has no radial or longitudinal support along its length and is not attached to a scaffold or frame structure. Due to the unsupported nature thereof, the flexible canopy **102** is permitted to conform to the underlying leaflet structure and further is non-traumatic to the surrounding native anatomy.

The size and perimeter of the flexible canopy **102** may be selected based upon the desired amount of leaflet coverage, the shape of the native anatomy, and/or desired anchoring positions. As best shown in FIG. **3**B, in an embodiment hereof, the flexible canopy **102** has an oblong shape and is configured to overlay the prolapsing leaflet of the native heart valve such that the first surface **114** of the flexible canopy is in contact with substantially the entire underlying surface (i.e., at least 90%) of the prolapsing leaflet of the native heart valve. In another embodiment hereof, the flexible canopy **102** is configured to overlay the prolapsing leaflet of the native heart valve such that the first surface **114** of the flexible canopy is in contact with between forty and ninety percent (40-90%) of the underlying surface of the prolapsing leaflet of the native heart valve. In addition, while the flexible canopy **102** of FIGS. **3**A and **3**B is shown with a particular length that extends distally a particular distance, this is by way of example and not limitation, and it will be understood that other lengths that are suitable to treat valvular regurgitation may be used. More particularly, as best shown in FIG. **3**B, in an embodiment the flexible canopy **102** extends distally beyond a distal end of the native posterior leaflet PL. However, in an alternative embodiment, the flexible canopy **102** does not extend beyond a prolapsing portion of the posterior leaflet PL. It will be understood that the shape and size of the flexible canopy **102** may assume any and all possible permutations including, but not limited to the flexible canopy **102** spanning most of the native prolapsing leaflet, spanning just past the prolapsing portion of the native prolapsing leaflet or any other configurations suitable for the purposes described herein.

The elongated tether **104** will now be described in more detail with reference to FIG. **3**A. The elongated tether **104** has a first length L**1** extending from a proximal end **120** thereof, which is attached to the distal end **108** of the flexible canopy **102**, to a distal end **122** thereof. The proximal end **120** of the elongated tether **104** may be coupled to the distal end **108** of the flexible canopy **102** by methods including but not limited to adhesives, tying, sutures, mechanical devices, fusing, or any other method suitable for the purposes described herein. The elongated tether **104** includes an elastic portion **124** coupled to an inelastic portion **126**. The elastic portion **124** is an elongate member having elastic qualities. As used herein, "elastic" means that the elongate member returns or is able to resume its original length or shape after distortion. The elastic portion **124** may be formed of elastic materials such as, but not limited to prosthetic chordae materials such as silicone, gore, Gore-tex®, or any other suitable material. When the system **100** is in the deployed configuration in situ, the elastic portion **124** is configured to allow for dynamic movement of the flexible canopy **102**. The inelastic portion **126** is an elongate member having inelastic qualities. As used herein, "inelastic" means that the elongate member **126** is not elastic and cannot be stretched. The inelastic portion **126** may be formed of inelastic materials such as, but not limited to a monofilament or plastic suture materials such as polypropylene, metal alloys such as stainless steel, titanium, or nickel-titanium alloys (i.e. NITINOL), or any other suitable material.

The elongated tether **104** is continuous or stated another way, the elastic portion **124** and the inelastic portion **126** collectively form the elongated tether **104**. The elastic portion **124** includes a proximal end **128** and a distal end **130**, while the inelastic portion **126** includes a proximal end **132** and a distal end **134**. In the embodiment of FIGS. **3-6**, the elastic portion **124** is disposed proximal of the inelastic portion **126**. More specifically, the proximal end **128** of the elastic portion **124** is coupled to the distal end **108** of the flexible canopy **102** and the distal end **130** of the elastic portion **124** is coupled to the proximal end **132** of the inelastic portion **126**. The proximal end **132** of the inelastic portion **126** may be coupled to the distal end **130** of the elastic portion **124** by methods including, but not limited to adhesives, tying, sutures, mechanical devices, fusing, or any other method suitable for the purposes described herein. The ratio of the elastic portion **124** to the inelastic portion **126** with reference to the first length L**1** of the elongated tether **104** is selected based on a variety of characteristics including, but not limited to the native valve location, the native anatomy, and the characteristics and geometry of the system **100**. In an embodiment hereof, as shown in FIGS. **3**A and **3**B, the elastic portion **124** is longer than the inelastic portion **126** to ensure that dynamic movement of the flexible canopy **102** is permitted in situ. For example, the ratio of the elastic portion **124** to the inelastic portion **126** of the elongated tether **104** may be 50/50, 60/40, 70/30, or other ratio found suitable for repairing valvular regurgitation.

The distal end **122** of the elongated tether **104** is coupled to a distal anchor (not shown in FIG. **3**A) which is anchored in a ventricle adjacent the prolapsing valve. The elongated tether **104** is configured to be placed into tension when the system **100** is in the deployed configuration and implanted in situ, as described in more detail below. When placed into tension, the elongated tether **104** pulls on the distal end **108** of the flexible canopy **102** in a distal direction as indicated by a directional arrow **150**. Stated another way, when the elongated tether **104** is placed into tension during implan-

tation, the elongated tether **104** places the flexible canopy **102** into tension. Further, the tension on the elongated tether **104** is configured to be adjustable in situ to adjust or tune the curvature of the flexible canopy **102** and/or the angle at which the flexible canopy **102** coapts with the non-prolapsing leaflet or leaflets of the heart valve to minimize or reduce regurgitation. When the tension applied to the elongated tether **104** is increased, the elastic portion **124** of the elongated tether **104** stretches or elongates and the first length L**1** of the elongated tether **104** relatively increases. Conversely, when the tension applied to the elongated tether **104** is decreased, the elastic portion **124** of the elongated tether **104** shortens and the first length L**1** of the elongated tether **104** relatively decreases. Devices and methods for placing the elongated tether **104** into tension will be discussed in more detail with respect to FIG. **4** below.

The interaction of the components of the system **100** will now be described with reference to FIGS. **4-6**. FIGS. **4** and **5** are schematic sectional illustrations of the system **100** in a deployed configuration implanted within a heart HE, with FIG. **4** illustrating a native mitral valve MV of the heart in an open configuration and FIG. **5** illustrating the native mitral valve MV of the heart HE in a closed configuration. FIG. **6** is a top view illustration of the native mitral valve MV of the heart HE in the closed configuration. Within FIGS. **4-6**, the direction of blood flow is indicated by arrows BF. The system **100** is configured to repair a prolapsing posterior leaflet PL of the mitral valve MV. More particularly, when the system **100** is in the deployed configuration and implanted within the heart HE, the proximal end **106** of the flexible canopy **102** is anchored or coupled to an annulus AN of the mitral valve MV by at least one proximal anchor **136**. The first surface **114** of the flexible canopy **102** overlays and is in contact with an underlying first surface of the first or posterior leaflet PL of the mitral valve MV. The elongated tether **104** extends from the distal end **108** of the flexible canopy **102** to a distal anchor **138** in the left ventricle LV.

The proximal and distal anchors **136**, **138** may be of any anchor suitable for embedding into the tissue of the annulus AN and the left ventricle LV, respectively, including but limited to helical screws or anchors, barbs, or clips. In the embodiment illustrated in FIGS. **4** and **5**, each of the proximal anchors **136** and the distal anchor **138** are shown as helical screws or anchors. Each helical anchor **136**, **138** is rotatable by a corresponding releasable shaft of a delivery catheter to embed the respective helical anchor in myocardial tissue. For example, and not by way of limitation, each of the proximal and distal anchors **136**, **138** may be an anchor as described in U.S. Pat. No. 3,974,834 to Kane or U.S. Pat. No. 4,046,151 to Rose, each of which is assigned to the same assignee of the present invention and each of which is hereby incorporated by reference in its entirety herein. While described herein as helical anchors **136**, **138**, this is by way of example and not limitation and the shape of the proximal and distal anchors **136**, **138** may have other shapes and other methods for delivery. For example, and not by way of limitation, the proximal and/or distal anchors **136**, **138** may be an anchor as described in U.S. Pat. No. 4,341,226 to Peters or U.S. Pat. No. 9,775,982 to Grubac et al., each of which is assigned to the same assignee of the present invention and each of which is hereby incorporated by reference in its entirety herein.

As described above, when the system **100** is in the deployed configuration and implanted in situ as shown in FIG. **4**, the elongated tether **104** is placed into tension in order to properly position the flexible canopy **102** to overlay the underlying first surface of the first or posterior leaflet PL of the mitral valve MV. In an embodiment hereof, the distal end **122** of the elongated tether **104** is pre-attached to the distal anchor **138** and the elongated tether **104** is placed into tension by attaching the distal anchor **138** to the left ventricle LV in such a way that provides tension to the elongated tether **104**. More particularly, tension is provided to the elongated tether **104** by varying the amount that the distal anchor **138** is advanced or embedded into a wall of the left ventricle LV. For example, when the distal anchor **138** is a helical screw as shown, the distal anchor **138** may be screwed into the wall of the left ventricle LV a greater amount or distance to increase the tension applied to the elongated tether **104**. Conversely, the distal anchor **138** may be unscrewed to decrease the tension applied to the elongated tether **104**, if desired. In another embodiment hereof, the distal end **122** of the elongated tether **104** is pre-attached to the distal anchor **138**, and the elongated tether **104** is placed into tension by varying the angle at which the elongated tether **104** extends from the flexible canopy **102**. More particularly, the location of the distal anchor **138** may be moved to increase or decrease the angle at which the elongated tether **104** extends from the flexible canopy **102**. For example, the location of the distal anchor **138** may be moved towards the apex AP of the left ventricle LV to increase the tension applied to the elongated tether **104**. Conversely, the location of the distal anchor **138** may be moved towards the interventricular septum IVS of the left ventricle LV to decrease the tension applied to the elongated tether **104**.

In another embodiment hereof, the elongated tether **104** is configured to be placed into tension via a tensioning device or tensioner (now shown). For example, a tensioning device as described in U.S. Pat. No. 9,452,048 to O'Bierne et al., assigned to the same assignee of the present invention and which is hereby incorporated by reference in its entirety herein, may be modified and utilized as a tensioning device or tensioner. For example, the elongated tether **104** may initially be slidably coupled to the distal anchor **138** via an integral loop of the elongated tether **104** such that a free end of the elongated tether **104** extends proximally through a delivery catheter and is accessible to the physician. After the distal anchor **138** is secured to the wall of the ventricle, the physician may pull on the accessible free end of the elongated tether **104** to effectively decrease the first length L**1** of the elongated tether **104** in situ and further effectively increase the tension placed on the elongated tether **104**. Conversely, the physician may release or push the free end of the elongated tether **104** to effectively increase the first length L**1** of the elongated tether **104** in situ and further effectively decrease the tension placed the elongated tether **104**. Once the tension is optimized, a locking mechanism as described in U.S. Pat. No. 9,452,048 to O'Bierne et al., previously incorporated by reference above, may be slid or advanced over the free end of the elongated tether **104** and through the delivery catheter until the locking mechanism abuts against the distal anchor **138** and thereby secures the position of the elongated tether **104** being placed under the desired amount of tension. Any excess length of the elongated tether **104**, i.e., the length of tether extending from the locking mechanism to the free end extending proximally back to the physician, may be cut and removed from the patient. A tensioning device has been described herein by way of example and not limitation. It will be understood that the tensioning device may be any suitable device configured to permit the elongated tether **104** to be placed into tension, and more specifically to adjust or change the first length L**1**

of the elongated tether **104** to increase or decrease the amount of tension placed onto the elongated tether **104** as described above.

Regardless of which method or device is used to place the elongated tether **104** into tension, the first length L**1** of the elongated tether **104** is varied during adjustment of the tension placed on the elongated tether **104**. Accordingly, when the first length L**1** of the elongated tether **104** is reduced to increase the tension placed on the elongated tether **104**, the elastic portion **124** thereof is stretched. Because of the desire of the elastic portion **124** to return to its resting shape or length, the elastic portion **124** is placed into spring tension. This spring tension is transferred to adjacent coupled components as a tension force. More precisely, the spring tension pulls on the proximal end **132** of the inelastic portion **126** and is transferred through the inelastic portion **126** to the distal end **122** of the elongated tether **104** anchored to the left ventricle LV by the distal anchor **138** with a first tension force represented by a directional arrow TF**1** illustrated in FIG. **5**. Further, the spring tension pulls on the distal end **108** of the flexible canopy **102** and is transferred through the flexible canopy **102** to the proximal end **106** of the flexible canopy **102** anchored at the annulus AN by the at least one proximal anchor **136** with a second tension force represented by a directional arrow TF**2** illustrated in FIG. **5**. For the purposes described herein, the distal anchor **138** and the at least one proximal anchor **136** are stationary relative to the system **100**. It will be understood that the first and second tension forces TF**1** and TF**2** are equal and opposite. The distal end **108** of the flexible canopy **102** is pulled in the direction of the arrow TF**2** with sufficient tension force that the flexible canopy **102**, or more precisely the first surface **114** thereof is placed into contact with the underlying first surface of the posterior leaflet PL, and thereby prevents the posterior leaflet PL from prolapsing. Further, the tension force on the flexible canopy **102** may be adjusted to optimize coaptation of the flexible canopy **102** with the second leaflet of the heart valve, and to minimize valvular regurgitation. Stated another way, the tension force on the elongated tether **104** is adjustable to maximize coaptation of a portion of the second surface **116** of the flexible canopy **102** with an opposing mating portion of an anterior leaflet AL of the mitral valve MV, and to minimize or eliminate regurgitation at the mitral valve MV.

While shown with three proximal anchors **136** in specific locations in FIG. **6**, this is by way of example and not limitation. It will be understood that more or fewer proximal anchors **136** may be used, and that the proximal anchor(s) **136** may be disposed at other locations. Further, while the distal anchor **138** is shown in FIG. **5** disposed at the apex AP of the left ventricle LV, this too is by way of example and not limitation. The distal anchor **138** may be disposed at any location within the left ventricle LV to optimize an angle between the coapting surfaces of the flexible canopy **102** and the anterior leaflet AL. For example, the distal anchor **138** may be disposed at any location within the left ventricle LV including, but not limited to the apex AP, the ventricle wall, the interventricular septum IVS, or the papillary muscle PM.

FIG. **7**A is a perspective view of a system **200** for treating regurgitation of a heart valve due to a prolapsing leaflet and configured in accordance with another embodiment hereof. The system **200** includes a flexible canopy **202** and an elongated tether **204**, the elongated tether **204** including an elastic portion **224** and an inelastic portion **226**. In the embodiment in FIG. **7**A, the flexible canopy **202** includes a frame **242** and the elongated tether **204** has an alternative configuration than the elongated tether **104** described above.

As shown in FIG. **7**A, the flexible canopy **202** is formed of a flexible material and is similar to the flexible canopy **102** previously described. Therefore, similar details of the configuration and materials of the flexible canopy **202** will not be repeated. However, the flexible canopy **202** is supported by a frame **242** coupled to the material of the flexible canopy **202**. The frame **242** is disposed at a proximal portion **248** of the flexible canopy **202**. In the embodiment of FIG. **7**A, the frame **242** has a D-shaped configuration and a first or curved end portion **244** of the frame **242** is disposed adjacent a proximal end **206** of the flexible canopy **202**. The frame **242** is disposed adjacent to a perimeter of the flexible canopy **202** and the frame **242** further generally follows the shape of the perimeter of the flexible canopy **202**. However, this is not meant to be limiting, and it will be understood that the frame **242** may be disposed at any location of the flexible canopy **202**. In embodiments hereof, the frame **242** is configured to provide structural support to a proximal portion **248** of the flexible canopy **202**. Further, the frame **242** serves to maintain coaptation angles between the flexible canopy **202** and the non-prolapsing leaflet or leaflets of the heart valve when the system **200** is in a deployed configuration and the heart valve is in a closed configuration. While shown with a specific shape, the frame **242** may have other shapes including but not limited to an ellipse, a circle, or any other shape suitable for the purposes described herein. Further, embodiments of the frame **242** may include additional struts or other strengthening members. The frame **242** may be formed of materials such as, but not limited to nickel titanium alloys (e.g. NITINOL), stainless steel, or other suitable materials. The frame **242** may be sewn into the flexible canopy **202** or may be coupled to the flexible canopy **202** by any other suitable method. In an embodiment, the frame **242** is attached to a plurality of proximal anchors **236**.

In the embodiment of FIG. **7**A, the frame **242** is configured to be disposed only on the atrial side of the native mitral valve when the system **200** is in a deployed configuration in situ. When the frame **242** is disposed only on the atrial side of the native mitral valve, the flexible canopy **202** is permitted to have increased flexibility within the left ventricle. Further, with the frame **242** disposed only on the atrial side of the native mitral valve, there are no relatively rigid or stiff elements of the frame **242** within the left ventricle LV that have potential to damage the chordae or other native anatomy within the left ventricle LV. In an alternate embodiment, the frame **242** may extend distally into the adjacent ventricle.

The elongated tether **204** of FIG. **7**A is similar to the elongated tether **104** of FIG. **3**A, except that the configuration or arrangement of the elastic and inelastic portions **224**, **226**, respectively are reversed from the configuration of the elongated tether **104** shown in FIG. **3**A. More particularly, in the embodiment of FIG. **7**A, the elastic portion **224** is disposed distal of the inelastic portion **226**. The elastic portion **224** includes a proximal end **228** and a distal end **230**. In the embodiment of FIG. **7**A, the elastic portion **224** is a helical spring. As with the elastic portion **124** of FIG. **3**A, the elastic portion **224** is configured to impart a tension force on the flexible canopy **202** as previously described with respect to the elastic portion **124** of FIG. **3**A, and therefore is not described in detail with respect to FIG. **7**A.

The configuration of the inelastic portion **226** of the elongated tether **204** of FIG. **7**A includes a proximal end **232** coupled to the distal end **208** of the flexible canopy **202**, a distal end **234** of the inelastic portion **226** coupled to the

proximal end **228** of the elastic portion **224**, and the distal end **230** of the elastic portion **224** coupled to the ventricle as previously described with respect to the distal end **134** of FIGS. **4-6**. While the inelastic portion **226** and the elastic portion **224** are positioned at opposite ends of the elongated tether **204** than the elastic portion **124** and the inelastic portion **126** of the elongated tether **104** of FIG. **3**A, it will be understood that applying and adjusting the tension force on the flexible canopy **202** is similarly accomplished by lengthening or shortening the length of the elongated tether **204**.

While described herein with one (1) spring elastic portion **224**, in an alternative embodiment, an elongated tether **204'** includes two (2) spring elastic portions **224***a* and **224***b*, disposed at the proximal end **232'** and the distal end **234'**, respectively, of the inelastic portion **226'**, as shown in FIG. **7**B. The two spring elastic portions **224***a* and **224***b* help to ensure that dynamic movement of the flexible canopy **202** is permitted in situ.

FIGS. **8-14** are sectional cut-away views of a heart HE illustrating method steps of treating regurgitation at a mitral valve MV via a transseptal approach for delivering and deploying the system **100** of FIG. **3** in accordance with an embodiment hereof. Access to the mitral valve MV can be accomplished through a patient's vasculature in a percutaneous manner. In an embodiment, the approach to the mitral valve is antegrade and may be accomplished via entry into the left atrium by crossing the interatrial septum. As is known in the art, a guidewire (not shown) may be advanced intravascularly using any number of techniques, e.g., through the inferior vena cava or superior vena cava (FIG. **1**), into the right atrium RA through a penetration hole cut in the inter-atrial septum (not shown) and into the left atrium LA (FIG. **1**). A guide catheter (not shown) may be advanced along the guidewire and into the right atrium RA, through the penetration hole in the inter-atrial septum, and into the left atrium LA. The guide catheter may have a pre-shaped or steerable distal end to shape or steer the guide catheter such that it will direct a delivery catheter toward the mitral valve MV.

Alternatively, the mitral valve may also be accessed via a transatrial approach for e.g., directly through an incision in the left atrium LA. Access to the heart may be obtained through an intercostal incision in the chest without removing ribs, and a guiding catheter (not shown) may be placed into the left atrium LA through an atrial incision sealed with a purse-string suture. A delivery catheter may then be advanced through the guiding catheter to the mitral valve. Alternatively, the delivery catheter may include a guidewire lumen such that it may be tracked over a guidewire and placed directly through the atrial incision without the use of a guiding catheter.

Referring to FIG. **8**, a distal segment **303** of a delivery catheter **301** is shown positioned in the left atrium LA. The delivery catheter **301** is delivered through the vasculature into the left atrium LA with the system **100** in a delivery configuration, in which the system **100** is radially compressed and disposed within the distal segment **303** of the delivery catheter **301**. Intravascular access to the right atrium RA may be achieved via a percutaneous access site in a femoral, brachial, radial, or axillary artery. As will be understood by those knowledgeable in the art, a handle component (not visible in FIGS. **8-14**), as well as some length of a proximal segment of the delivery catheter **301**, are exposed externally of the patient for access by a clinician. By manipulating the handle of the delivery catheter **301** from outside the vasculature, a clinician may advance and remotely manipulate and steer the distal segment **303** of the delivery catheter **301** through the sometimes tortuous intravascular path. The distal segment **303** of the delivery catheter **301** may be distally advanced into the left atrium LA and positioned generally above (e.g., upstream) the mitral valve MV to deliver the system **100** to the mitral valve MV.

In a next delivery step shown in FIG. **9**, three proximal anchors **136** are embedded in tissue at an annulus AN of the mitral valve MV. Embedding of each proximal anchor **136** at the annulus AN may be accomplished by various methods understood by those knowledgeable in the art. For example, and not by way of limitation, each proximal anchor **136** may be a helical anchor, rotated by a respective proximal anchor shaft **305** of the delivery catheter **301** to embed each proximal anchor **136** into tissue at the annulus AN. Each proximal anchor shaft **305** may be a shaft, rod, or lead as described, for example, in U.S. Pat. No. 3,974,834 or 4,046,151, each of which has previously been incorporated by reference in its entirety. Once each proximal anchor **136** is embedded at the annulus AN, the proximal anchor **136** is released from the respective proximal anchor shaft **305**.

In the embodiment of FIG. **9**, each proximal anchor **136** is pre-attached to the flexible canopy **102** prior to delivery with the delivery catheter **301**. Thus, once the proximal anchors **136** are embedded at the annulus AN and each proximal anchor **136** is released from the respective proximal anchor shaft **305**, the proximal end **106** of the flexible canopy **102** remains attached to each of the proximal anchors **136** at the annulus AN, as shown in FIG. **10**. The proximal end **106** is attached to the plurality of proximal anchors **136** to effectively anchor or secure the proximal end **106** of the flexible canopy **102** to the annulus AN of the native mitral valve MV.

While described herein with the flexible canopy **102** pre-attached to the plurality of proximal anchors **136** prior to delivery by the delivery catheter **301**, this is by way of example and not limitation. It will be understood that the flexible canopy **102** can alternatively be coupled to the plurality of proximal anchors **136** after each of the proximal anchors **136** has been embedded at the annulus AN of the native mitral valve MV. For example, and not by way of limitation, the flexible canopy **102** may include a plurality of eyelets attached thereto with each proximal anchor shaft **305** disposed through a corresponding eyelet. The flexible canopy **102** can be deployed from the delivery catheter **301** by a push shaft or other device, and each eyelet and the flexible canopy **102** slide distally along the respective plurality of proximal anchor shafts **305** to couple to the corresponding proximal anchors **136**. Once the flexible canopy **102** is coupled to the plurality of proximal anchors **136**, each proximal anchor **136** is released by the respective proximal anchor shaft **305**.

As shown in FIG. **11**, in a next step the distal anchor **138** is embedded in tissue within the left ventricle LV with a distal anchor shaft **307**. Embedding of the distal anchor **138** may be accomplished by various methods understood by those knowledgeable in the art. For example, and not by way of limitation, the distal anchor **138** may be a helical anchor, rotated by the distal anchor shaft **307** to embed the distal anchor **138** in an apex AP of the left ventricle LV. The distal anchor shaft **307** may be a shaft, rod, or lead as described, for example, in U.S. Pat. No. 3,974,834 or 4,046,151 assigned to Medtronic, Inc., each of which has previously been incorporated by reference in its entirety. While shown with the distal anchor **138** embedded in tissue at an apex AP of the left ventricle LV, this is by way of example and not

limitation. As previously described, the location of the distal anchor **138** within the left ventricle LV may be determined based upon the angle of the flexible canopy **102** in relation to the anterior leaflet AL to achieve optimal coaptation between the flexible canopy **102** and the anterior leaflet AL to minimize or eliminate regurgitation. Once the distal anchor **138** is embedded at the desired location of the left ventricle LV, the distal anchor **138** is released from the distal anchor shaft **307**.

In the embodiment of FIG. **11**, the distal anchor **138** is pre-attached to the elongated tether **104** prior to delivery with the delivery catheter **301**. Accordingly, once the distal anchor **138** is embedded in the left ventricle LV and the distal anchor **138** is released from the distal anchor shaft **307**, the distal end **122** of the elongated tether **104** is attached to the distal anchor **138**, as shown in FIG. **12**. The distal end **122** is attached to the distal anchor **138** to effectively secure or anchor the distal end **122** of the elongated tether **104** to the left ventricle LV.

Although the elongated tether **104** has been described as coupled to the distal anchors **138** prior to delivery by the delivery catheter **301**, this is by way of example and not limitation. It will be understood that the elongated tether **104** may alternatively be delivered separately and coupled to the distal anchor **138** after the distal anchor **138** has been embedded in the left ventricle LV. For example, and not by way of limitation, the elongated tether **104** can include an eyelet at the distal end **122** with the distal anchor shaft **307** disposed through the eyelet of the elongated tether **104**. The elongated tether **104** can be deployed from the delivery catheter **301** by a push shaft or other device, and the eyelet and the elongated tether **104** slid distally along the distal anchor shaft **307** to couple to the eyelet of the elongated tether **104** to the distal anchor **138**. Once the elongated tether **104** is coupled to the distal anchor **138**, the distal anchor **138** is released by the distal anchor shaft **307**.

When the proximal end **106** of the flexible canopy **102** is coupled to the annulus AN and the distal end **122** of the elongated tether **104** is coupled to the left ventricle LV, with the flexible canopy **102** overlaying the posterior leaflet PL, tension is applied and/or adjusted as described above with respect to FIGS. **4** and **5** to apply a tension force on the flexible canopy **102**. More precisely, as described above in more detail, the elastic portion **124** of the elongated tether **104** is placed under spring tension and the spring tension on the elastic portion **124** is transferred to the distal end **108** of the flexible canopy **102** as a second tension force TF**2** as indicated by the arrow TF**2**. The second tension force TF**2** on the flexible canopy **102** prevents the posterior leaflet PL from prolapsing and insures coaptation of the flexible canopy **102** with the anterior leaflet AL, as shown in FIG. **13**.

In a next step, the mitral valve MV is checked for valvular regurgitation. Checking for regurgitation of the mitral valve MV may be accomplished by various methods including, but not limited to echocardiogram, to visualize placement of the flexible canopy **102** and prolapse of the posterior leaflet PL of the mitral valve MV. Accordingly, an echogenic coating may be applied to one or more integral portions of the system **100** to aid in visualization. When the mitral valve MV has been checked for valvular regurgitation, the treating clinician may further adjust the tension force on the flexible canopy **102** to minimize valvular regurgitation and optimize coaptation of the flexible canopy **102** with the anterior leaflet AL, as shown in FIG. **14**. The steps of checking for valvular regurgitation and readjusting the tension force on the flexible canopy **102** may be repeated to optimize performance of the repaired mitral valve MV. Following delivery, deployment and adjustment of the system **100** at the mitral valve MV (or other desired valve location), the delivery catheter **301** and remaining guidewire (if any) may be removed from the heart **10** and out of the body of the patient.

Image guidance, enhanced echogenicity, or other methods may be used to aid the clinician's delivery and positioning of the system **100**. Image guidance, e.g., intracardiac echocardiography (ICE), fluoroscopy, computed tomography (CT), intravascular ultrasound (IVUS), optical coherence tomography (OCT), or another suitable guidance modality, or combination thereof, may be used to aid the clinician's positioning and manipulation of the system **100** at the target native valve region. For example, such image guidance technologies can be used to aid in determining the positioning of the flexible canopy **102** with relation to the underlying, prolapsing native leaflet. In some embodiments, image guidance components (e.g., IVUS, OCT) can be coupled to the distal portion of the delivery catheter **301**, a guide catheter, or both to provide three-dimensional images of the area proximate to the target heart valve region to facilitate positioning, orienting and/or deployment of the system **100** within the heart valve region. Accordingly, an echogenic coating may be applied to components of the system to aid in visualization.

Various method steps described above for delivery and deployment of embodiments of the system within a native heart valve of a patient may also be interchanged to form additional embodiments of the present technology. For example, while the method steps described above are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

Furthermore, while the delivery catheter described above is discussed as being suitable for delivering embodiments of the system to the native mitral valve using a transseptal approach, it will be understood that the delivery catheter may also be suitable for delivering systems for repair of other heart valves (e.g., pulmonary valve, tricuspid valve, etc.) and utilizing other approaches (e.g. retrograde, antegrade). Various arrangements of the delivery catheters suitable for use with embodiments of systems and methods described herein may also be used to deliver other therapeutic or medical tools within body lumens.

While various embodiments have been described above, it should be understood that they have been presented only as illustrations and examples of the present technology, and not by way of limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail may be made therein without departing from the spirit and scope of the present technology. Thus, the breadth and scope of the present technology should not be limited by any of the above-described embodiments, but should be defined only in accordance with the appended claims and their equivalents. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, may be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

What is claimed is:

1. A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:

a flexible canopy including a first surface and a second surface opposite the first surface;

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein the elastic portion is at least as long as the inelastic portion with a ratio of the elastic portion to the inelastic portion being between 50/50 and 70/30 and a proximal end of the elongated tether is attached to a distal end of the flexible canopy; and

a distal anchor configured to be embedded into tissue of a ventricle, wherein a distal end of the elongated tether is coupled to the distal anchor,

wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and the distal end of the elongated tether is anchored to tissue of a ventricle via the distal anchor such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

2. The system of claim **1**, wherein when the first surface of the flexible canopy overlays the first leaflet of the heart valve, the first surface of the flexible canopy is substantially in contact with between forty and ninety percent of the underlying first surface of the first leaflet of the heart valve.

3. The system of claim **1**, wherein the flexible canopy does not extend into the ventricle when the system is in the deployed configuration.

4. The system of claim **1**, wherein the inelastic portion of the elongated tether is positioned distal of the elastic portion of the elongated tether.

5. The system of claim **1**, wherein the elastic portion of the elongated tether is positioned distal of the inelastic portion of the elongated tether.

6. The system of claim **1**, wherein the elastic portion of the elongated tether is longer than the inelastic portion of the elongated tether.

7. The system of claim **1**, wherein the elastic portion of the elongated tether is a spring.

8. The system of claim **1**, further comprising: a frame coupled to a portion of the flexible canopy.

9. The system of claim **8**, wherein the frame does not extend into the ventricle when the system is in the deployed configuration.

10. The system of claim **1**, wherein the flexible canopy is unsupported and does not include a frame coupled thereto.

11. The system of claim **1**, wherein the flexible canopy extends into the ventricle when the system is in the deployed configuration.

12. A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:

a flexible canopy including a first surface and a second surface opposite the first surface; and

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein the elastic portion is at least as long as the inelastic portion and a proximal end of the elongated tether is attached to a distal end of the flexible canopy,

wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and a distal end of the elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve, and

wherein the first surface of the flexible canopy includes at least one micro-barb and the at least one micro-barb is configured to couple the first surface of the flexible canopy to the underlying first surface of the first leaflet of the heart valve.

13. A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:

a flexible canopy including a first surface and a second surface opposite the first surface, wherein the flexible canopy is unsupported and does not include a frame coupled thereto; and

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein a ratio of the elastic portion to the inelastic portion is between 50/50 and 70/30, and wherein a proximal end of the elongated tether is attached to a distal end of the flexible canopy; and

a distal anchor configured to be embedded into tissue of a ventricle, wherein a distal end of the elongated tether is coupled to the distal anchor,

wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and the distal end of the elongated tether is anchored to tissue of a ventricle via the distal anchor such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

14. The system of claim **13**, wherein when the first surface of the flexible canopy overlays the first leaflet of the heart valve, the first surface of the flexible canopy is substantially in contact with between forty and ninety percent of the underlying first surface of the first leaflet of the heart valve.

15. The system of claim **13**, wherein the first surface of the flexible canopy includes at least one micro-tine and the at least one micro-tine is configured to couple the first surface of the flexible canopy to the underlying first surface of the first leaflet of the heart valve.

16. The system of claim **13**, wherein the flexible canopy does not extend into the ventricle when the system is in the deployed configuration.

17. The system of claim **13**, wherein the flexible canopy extends into the ventricle when the system is in the deployed configuration.

18. The system of claim **13**, wherein the inelastic portion of the elongated tether is positioned distal of the elastic portion of the elongated tether.

19. The system of claim **13**, wherein the elastic portion of the elongated tether is positioned distal of the inelastic portion of the elongated tether.

20. The system of claim **13**, wherein the elastic portion of the elongated tether is longer than the inelastic portion of the elongated tether.

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